UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION *This document relates to:* Track One Cases	MDL 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

PLAINTIFFS' CONSOLIDATED MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT ON PLAINTIFFS' CIVIL CONSPIRACY, RICO AND OCPA CLAIMS (DKT. # 1692, 1716, 1904, 1930)

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GLOSSARY

AAPM	American Academy of Pain Medicine
ABDC	AmerisourceBergen Drug Corporation
ADIWG	Anti-Diversion Industry Working Group
AGS	American Geriatric Society
APCO	APCO Worldwide, a public affairs and strategic communications consultancy
APF	American Pain Foundation
APS	American Pain Society
CDC	Centers for Disease Control
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
FSMB	Federation of State Medical Boards
GAO	Government Accountability Office
GPhA	Generic Pharmaceutical Association
HCPs	Hydrocodone Combination Products
HDA	Healthcare Distribution Alliance
HDMA	Healthcare Distribution Management Association, Predecessor to HDA

GLOSSARY (CONT'D)

ICGs	Industry Compliance Guidelines
JCAHO	Joint Commission for Hospital Accreditation
KOL	Key Opinion Leader
LA/ER	Long-acting, Extended Release
NACDS	National Association of Chain Drug Stores
NJPIG	New Jersey Pharmaceutical Industry Working Group
NWDA	National Wholesale Druggists' Association, Predecessor to HAD
OCPA	Ohio Corrupt Practices Act
OMP	Order Monitoring Program
PCF	Pain Care Forum
PhRMA	Pharmaceutical Research and Manufacturers of America
PPSG	Wisconsin Pain and Policy Studies Group
REMS	Risk Evaluation and Mitigation Strategies
RICO	Racketeer Influenced and Corrupt Organizations Act
SOM/SOMS	Suspicious Order Monitoring/Suspicious Order Monitoring System
SOTF	Suspicious Order Task Force
The Big Four	AmerisourceBergen, Cardinal Health, McKesson, and H.D. Smith
The Big Three	AmerisourceBergen, Cardinal Health, and McKesson

INTRODUCTION

Defendants—manufacturers, distributors, and pharmacies engaged in the business of selling and distributing prescription opioid drugs—move for summary judgment[1] on Plaintiffs' claims for civil conspiracy, violation of the Ohio Corrupt Practices Act (OCPA), and violation of the Racketeer Influence and Corrupt Organizations Act (RICO). Significantly, Defendants here do not challenge that they have committed unlawful acts necessary to establish a RICO or civil conspiracy violation. Instead, Defendants contend that summary judgment is appropriate because there is no evidence that Defendants agreed to do anything, much less anything unlawful. Rather, they portray themselves solely as legitimate businesses that operated independently and competitively within the law.

The summary judgment record, however, paints a different portrait. That record shows that the Defendants coordinated, combined, and constantly communicated with each other for the common purpose of maximizing sales of prescription opioids *beyond legal limits*. They accomplished this purpose through a common conspiracy comprising two schemes (and two RICO enterprises). The first (which encompasses the RICO Marketing Enterprise) was carried out by the Manufacturer Defendants, who engaged in a fraudulent marketing campaign that distorted the safety and efficacy of opioids and promoted the use of opioids to treat pain, all for the purpose of expanding the opioid market. The Manufacturer Defendants joined together to promote those false messages through direct partnerships, through organizations that they themselves created for precisely that purpose, through numerous experts and third-parties, and through organizations that set medical standards for practicing physicians. For competitors who should have been at each other's throats to gain market share, the record reveals that, instead, they partnered with each other to grow the opioid market

[1] This opposition responds to the following four motions: Manufacturers' Joint Motion for Summary Judgment on Plaintiffs' RICO, OCPA, and Conspiracy Claims (Dkt. # 1930); Distributor Defendants' Motion for Summary Judgment on Plaintiffs' RICO and OCPA Claims (Dkt. # 1904); Distributor Defendants' Motion for Summary Judgment on Civil Conspiracy Claim (Dkt. # 1692); Pharmacy Defendants' Motion for Summary Judgment on Plaintiffs' Civil Conspiracy Claim (Dkt. # 1716).

beyond the legal restrictions of the controlled substances drug market, and even protected and defended each other when the media bore down on them in light of the burgeoning opioid epidemic.

The second scheme (which encompasses the RICO Supply Chain Enterprise), in which the Distributor and Pharmacy Defendants joined, was to protect the opioid supply chain (i.e., ensuring that orders of opioids resulted in sales and receipt by the ultimate customer), including from federal laws designed to protect against the diversion of controlled substances. Together, the Manufacturer, Distributor, and Pharmacy Defendants all gamed the system to avoid compliance with the Controlled Substances Act; purposefully misled DEA that they would cooperate with DEA's enforcement efforts to stave off enforcement actions; and coordinated to "gang up on the DEA" to make enforcement even more difficult. This was not innocent or independent activity geared towards maximizing profits within the confines of the law. In complete disregard of the escalating diversion problem and the public health crisis stemming from the opioid epidemic, of which Defendants were admittedly aware, Defendants made the decision to band together to protect their commercial interests above all else, by making sure that sales were not disrupted by legitimate federal regulation.

Although the summary judgment record may not include a signed agreement to document Defendants' meeting of the minds, the evidence demonstrates an extensive web of Defendants' interrelationships, coordination, and common goal, which is more than sufficient to permit a jury to conclude that Defendants engaged in an overarching opioid conspiracy (comprised of two RICO enterprises) to grow and expand the opioid market and protect their businesses (and profits) from regulatory interference. This Court should deny Defendants' motions for summary judgment.

THE OPIOID CONSPIRACY – OVERVIEW

A. The Conspirators

The conspiracy defendants include manufactures, distributors, and pharmacies who sell and distribute prescription opioids. The Manufacturer Defendants are Purdue, Mallinckrodt, Endo,

Teva/Cephalon/Actavis,[2] and Janssen. The Distributor Defendants are AmerisourceBergen, Cardinal Health, McKesson, Anda, H.D. Smith, Prescription Supply, and Henry Schein. The Pharmacy Defendants are Walgreens, CVS, Walmart, Rite Aid, HBC, and Discount Drug Mart. Collectively, they are referred to herein as Defendants.

The overall conspiracy encompassed two RICO enterprises: the Marketing Enterprise and the Supply Chain Enterprise. The following RICO Manufacturer Defendants were participants in the Marketing Enterprise: Purdue, Mallinckrodt, Endo, Teva/Cephalon, and Janssen. The Supply Chain Enterprise included two groups of defendants: the RICO Manufacturer Defendants (except for Janssen) plus Actavis, and the RICO Distributor Defendants, which are AmerisourceBergen, Cardinal Health, and McKesson (collectively known as the "Big Three"). Altogether, these defendants are the RICO Defendants (which include all of the Manufacturer Defendants and three of the Distributor Defendants).

B. The Purpose

The common goal of the conspiracy, and of the RICO enterprises that furthered that conspiracy, was to dramatically expand the opioid market in the United States, including by evading diversion control requirements, so that the conspirators could reap the profits. By improperly expanding the use and availability of opioids in unprecedented and highly dangerous amounts, the conspiracy was able to traffic in illicit drugs through the controlled substances supply chain, profiting from the massive injury to communities and their residents caused by the opioid epidemic.

C. The RICO / OCPA Enterprises

The conspiracy's common purpose was furthered through two, related RICO enterprises, the Marketing Enterprise and the Supply Chain Enterprise.

[2] Teva acquired Cephalon in 2001 and acquired Actavis (Allergan's generics business) in 2016. Teva also acquired Anda in 2016. *See* https://www.tevapharm.com/about/history/.

The Marketing Enterprise was carried out by the RICO Manufacturer Defendants (all Manufacturer Defendants except Actavis), who formed the enterprise to expand the market for prescription opioids by spreading fraudulent messages about their safety and efficacy through countless "neutral" third-parties, organizations, groups, and forums to promote increased sales of opioids.

The Supply Chain Enterprise consisted of the RICO Manufacturer Defendants (except Janssen), Actavis, and the RICO Distributor Defendants (collectively, "RICO Supply Chain Defendants"), who worked together to ensure that the increased demand for opioids materialized into actual sales and profits. To that end, the RICO Supply Chain Defendants coordinated to evade state and federal diversion controls which would have limited opioid sales and their profits.

D. The Vehicles for Cooperation and Coordination

The Defendants used three main industry associations as vehicles to further the conspiracy, namely the Pain Care Forum ("PCF"), Healthcare Distribution Alliance ("HDA"), and the National Association of Chain Drug Stores ("NACDS").[3] As explained below, these associations, as well as numerous others whose memberships often overlapped, served as forums where the defendants met, coordinated, and devised common strategies to effectuate the purpose of the conspiracy.

1. Pain Care Forum

Purdue employee, Burt Rosen, and others organized the Pain Care Forum in 2005.[4] The PCF was made up of Manufacturer Defendants, the Distributors' association (the HDA), other trade associations, numerous front groups,[5] the Federation of State Medical Boards ("FSMB"), and the manufacturer trade organization Pharmaceutical Research and Manufacturers Association

[3] Conspirators also worked through other Industry Associations including New Jersey Pharmaceutical Industry Group ("NJPIG"), Midwest Controlled Substance Discussion Group ("MWDG"), and Anti-Diversion Industry Working Group ("ADIWG").
[4] Burt Rosen Dep. (01/16/19), Dkt. # 1970-10 at 60:1-3.
[5] Front groups refer to organizations that were used by the Defendants to "front" their message.

("PhRMA").[6] Members met once a month in Washington D.C.[7] The meetings were not public and no official minutes were taken.[8] The group was a way for members to discuss, strategize, and take positions on various issues related to the opioid industry. The Pain Care Forum often served as a front for Defendants, allowing their efforts in furtherance of the conspiracy to remain anonymous.[9]

2. Healthcare Distribution Alliance

The Healthcare Distribution Alliance ("HDA") was formed to protect the supply chain and advance the interests of its members.[10] Members include all of the Distributor Defendants.[11] The Manufacturer Defendants are affiliate members.[12] HDA's Board of Directors consists of representatives from the "Big Three" distributors (AmerisourceBergen, Cardinal Health, and McKesson) and other distributor members.[13] HDA is principally financed by members' annual dues, which are assessed based on sales.[14] The majority of its dues come from payments by the Big Three; for example, AmerisourceBergen paid yearly membership dues in excess of $1 million.[15]

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[6] Rosen Dep. Dkt. # 1970-10 at 59:23-60:13; Exh. 1, PPLP004272094 at 96 (List of "Pain Care Forum Participating Organizations" includes manufacturer defendants Allergan, Teva (Cephalon), Mallinckrodt (Covidien), Endo, Johnson & Johnson, and Purdue Pharma; the Healthcare Distribution Management Association (HDA) and National Association of Chain Drug Stores (NACDS) and front groups such as the American Pain Society, American Academy of Pain Medicine, American Association for Pain Medicine, American Pain Foundation, Pain & Policy Studies Group, and Federation of State Medical Boards).

[7] Rosen Dep., Dkt. # 1970-10 at 61:1-2; 66:1-11.

[8] Rosen Dep., Dkt. # 1970-10 at 72:1-21; see also Exh. 2, PPLP004266177 at 788 ("We have always restricted media from coming to the Pain Care Forum as the meetings are completely off the record.")

[9] Exh. 3, PPLP004065294 (Explaining need to keep PCF media and congressional campaign a secret and there is no need to share your strategy with the other side."); Exh. 4, PPLP004051807 (On a PCF media program to oppose measures to adopt more restrictive REMS, "this program should be driven by the not-for-profit community, potentially with multiple industry sponsors")

[10] Kelly Dep., Dkt. # 1963-14 at 38 (HDA acts "on behalf of our core members which are the distributor members"); Fri Depo at 48, 95. The HDA was previously known as the Healthcare Distribution Management Association (HDMA), the National Wholesale Druggists' Association, and the Western Wholesale Druggists' Association. Kelly Dep., Dkt. # 1963-14 at 33-34. References to HDA in this brief include references to its predecessor organizations.

[11] Kelly Dep., Dkt. # 1963-14 at 36-37; Exh. 448, Rita Norton Dep. (01/09/19) at 59-60.

[12] Kelly Dep., Dkt. # 1963-14 at 37-38.

[13] Kelly Dep., Dkt. # 1963-14 at 38-39; Fri Dep., Dkt. # 1962-5 at 64.

[14] Fri Dep., Dkt. # 1962-5 at 108:3-112:7.

[15] Exh. 5, ABDCMDL00169889 (indicating membership payments above $1 million and payments in addition thereto); ML00055624 at 637-49 (providing suggested options to increase funding by increasing "Capped Company Dues" from $1.1 million up to, potentially, $1.75 million). Notably, the proposed increases in ML00055624 at 637-49 correspond to the increasing membership dues paid by ABDC reflected in ABDCMDL00169889, including 2018 membership dues of $1.5 million.

3. National Association of Chain Drug Stores

The Pharmacy Defendants and almost all Distributor Defendants were members of National Association of Chain Drug Stores ("NACDS")[16] and many held key executive roles. As controlling members of NACDS, the Distributor and Pharmacy Defendants have served on and run key governing committees within the organization. For example, Defendants have served on and repeatedly chaired NACDS's Board of Directors, which determines the "strategic plan and positions" of the organization.[17] During the last 12 years, representatives of CVS, Rite Aid, and Walgreens have always held Board of Directors or officer seats.[18] At various times, distributor representatives,

[16] *See* https://www.nacds.org/membership/directories/associate-companies/ ("NACDS Member Suppliers Directory, listing AmerisourceBergen, McKesson, Cardinal Health, Anda, H.D. Smith, Walgreens, CVS, Rite Aid, Walmart, HBC / Giant Eagle). *See also* Responses to Plaintiffs First Set of Interrogatories, No. 15. (HBC / Giant Eagle). *See also* https://www.nacds.org/membership/directories/chain-companies/ (Walgreens, CVS, Rite Aid, Walmart, HBC, DDM/Giant Eagle). Distributor Defendants Prescription Supply Inc. and Henry Schein were not members of NACDS.

[17] https://www.nacds.org/about/mission/.

[18] For example, in 2018, Walgreens, Rite Aid, Walmart representatives were elected for three-year board term. *See* Exh. 6, WAGMDL00593972. In 2017, Walgreens, CVS, Rite Aid, and Walmart representatives serve as officers and directors. *See* https://web.archive.org/web/20170601105028/https://www.nacds.org/About/Leadership/. In 2016, a Walgreens representative is elected as an officer, a representative from Walmart was elected to the executive committee. *See* Exh. 7, DDM00329674. In 2015, officers and directors include representatives from Walgreens, Walmart, Rite Aid, CVS, and Cardinal. *See* Exh. 8, WAGMDL00633966. In 2014, a Rite Aid representative is elected as an officer, and a Walmart representative is elected to a three-year board term. *See* Exh. 9, DDM00282297. In 2013, Rite Aid and Walmart representatives are elected as officers and to three year board terms. *See NACDS Announces 2013-2014 Officers, Welcomes New Board, Executive Committee Members during Annual Meeting*, PHARMACY TIMES, April 22, 2013. In 2012, Walgreens and Rite Aid representatives are elected as officers, and a CVS representative is elected to a three-year board term. *See* Allison Cera, *NACDS elects new 2012-2013 officers,* DRUG STORE NEWS, April 23, 2012. https://www.drugstorenews.com/pharmacy/nacds-elects-new-2012-2013-officers/. In 2011, a Walgreens representative is elected as an officer. Allison Cera, *NACDS elects new 2011-2012 officers at Annual Meeting,* DRUG STORE NEWS, May 2, 2011. http://www.navarro.com/images/news-media/news2011/DrugStore.pdf. In 2010, CVS and Walgreens representatives are elected as officers. *See* CSA Staff, *NACDS elects new officers*, CHAIN STORE AGE, April 26, 2010. https://www.chainstoreage.com/operations/nacds-elects-new-officers/. In 2009, a CVS representative is elected as an officer, and Walgreens, McKesson, Cardinal, and Rite Aid representatives are elected to a three-year board term. *See* Allison Cera, NACDS elects board of directors, Drug Store News, April 20, 2009, https://www.drugstorenews.com/pharmacy/nacds-elects-board-directors/. In 2007, officers and directors include representatives from Walgreens, Walmart, Rite Aid, and CVS. *See* https://web.archive.org/web/20070812232032/http://www.nacds.org/wmspage.cfm?parm1=367. In 2006, officers and directors include representatives from Walgreens, Walmart, CVS, and Rite Aid. *See* https://web.archive.org/web/20060427042739/http://www.nacds.org/wmspage.cfm?parm1=367.

including from Cardinal Health, McKesson, and AmerisourceBergen, have served on the NACDS Board[19] or key committees.[20]

NACDS worked closely with other trade organizations to which the Defendants belonged, including the HDA. HDA and NACDS viewed as important the strategic "alliance" between their organizations and their overlapping membership.[21] The Manufacturer Defendants also participated in NACDS meetings.[22]

FACTUAL BACKGROUND

I. THE MANUFACTURER DEFENDANTS' FRAUDULENT MARKETING SCHEME

To increase opioid sales, the Manufacturer Defendants promoted nearly identical false or misleading messages about the benefits and risks of prescription opioids that had no basis in reliable, scientific evidence.[23] Indeed, Purdue and Cephalon pled guilty to violating federal law by spreading false and misleading information to physicians about their prescription opioids, including that their drugs were less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications.[24]

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[19] *See, e.g.*, https://www.drugstorenews.com/pharmacy/nacds-elects-board-directors/ (representatives of McKesson and Cardinal Health elected to NACDS Board of Directors in 2009); https://www.supermarketnews.com/executive-changes/wakefern-s-chris-lane-named-nacds-chairman (representatives of McKesson and Cardinal Health elected to NACDS Board of Directors in 2019) (board of director membership is a three year term).

[20] Exh. 10, CVS-MDLT1-000121577 (McKesson on the NACDS Strategic Communications Committee with Walmart, Walgreens, Rite Aid, and CVS; Exh. 11, CVS-MDLT1-000102930 (Cardinal Health on the 2012 NACDS Executive Committee); Exh. 12, CAH_MDL2804_00886155. *See e.g.* Exh. 13, CAH_MDL2804_00861971 (Defendants Walgreens, Walmart, Rite Aid, CVS, HBC/Giant Eagle, CVS, Cardinal Health, and McKesson on policy council communications discussing coordination of opioid related plans and responses to government action related to the rising epidemic of drug diversion and abuse).

[21] Exh. 14, HDA_MDL_000158258; Exh. 15, HDA_MDL_000117141; Exh. 16, HDA_MDL_000117241; Exh. 17, HDA_MDL_000117082

[22] For example, in September 2012, Defendant Endo sent around "NACDS Follow Up" notes regarding meetings with AmerisourceBergen and a chain pharmacy distributor about SOM practices and the impact of DEA enforcement regarding Schedule II opioids on their business. *See* Exh. 18, ENDO-OPIOID_MDL-03355279; Exh. 19, ENDO-OPIOID_MDL-03355280; Exh. 20, ENDO-OPIOID_MDL-03355281.

[23] *See* Report of Matthew Perri, BS Pharm, PhD, Rph, Dkt. # 2000-19, at 73-151 and Schedule 10; Report of Anna Lembke, MD, Dkt. # 2000-10, at 4-98 and Appendix 1; Report of David Kessler, MD, Dkt. # 2000-8 at 28-291; Report of David S. Egilman, MD, MPH, Dkt. # 2000-5 at 60 (Opinion 7.9), 62, 70.

[24] In 2007, Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers by promoting OxyContin as "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications," paying over $600 million in penalties. *See* Exh. 21, PPLP004496559. In 2007, Cephalon pled guilty and paid $425 million to resolve claims that it marketed Actiq and two other drugs for off-

The undisputed record is that the Manufacturer Defendants' marketing messages were designed to "educate healthcare professionals" about chronic pain and purported to "reflect[] innovations in the prescription opioid market over time."[25] These false messages promoted a new medical consensus that centered around "the pain movement": that opioids could be widely used for any duration to treat non-cancer pain and that all pain needed to be treated.[26] As Richard Sackler, President of Purdue Pharma, stated, "the fate of our products [is] inextricably bound with the pain movement."[27] Purdue remarked to Cephalon and Johnson & Johnson about an article titled: "U.S. Is Working to Make Painkillers Harder to Obtain - Patients May Suffer. . ." that "this is what **we** have always said."[28]

A. The Marketing Strategy Begins To Take Shape

The purpose of these false and misleading messages was to grow the overall prescription opioid market. For example, a Purdue sales presentation stated that it has "several public relations initiatives" that are designed to "*Make the whole pie bigger, not only for us but for our competition as well.*"[29] This included "a media query initiative" that "trains medical experts to talk to the media, making sure articles and radio/TV shows that deal with pain are friendly to our point of view."[30] It also included "weekly feature stories about pain and its management in newspapers," and developing "materials for the Joint Commission on Accreditation for Healthcare Organizations (JCAHO)" that "will be distributed to hospitals across the country in our partnership with the American Pain Society."[31]

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label uses, including marketing Actiq for "non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use with patients who were not opioid tolerant." *See* https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

[25] Mfg Jt. Mt at 9.

[26] Exh. 22, PPLPC045000004928; Exh. 23, PPLPC037000007677

[27] Exh. 22, PPLPC045000004928 at PPLPC045000004929.

[28] Exh. 24, PPLPC022000045283 (emphasis added).

[29] Exh. 25, PDD8801201589 at Exh. 26, PDD8801201589.

[30] *Id.*

[31] *Id. See also*, Exh. 27, PDD8801320902 (slide presentation that makes the same points).

Janssen and Purdue discussed coordinating as early as 2000 about "a co-promotion arrangement" related to opioids.[32] Even though they were competitors, Janssen and Purdue discussed jointly marketing their opioid products and how to grow the market as a whole, terming their collaboration "a powerful combination."[33] By October of 2000, "Project Pearl ha[d] been initiated to see if [Janssen] and Purdue can work together to create a pain franchise."[34]

However, any direct-to-consumer advertising containing Defendants' pro-opioid messages ran a substantial risk of FDA enforcement, as they well knew.[35] Nevertheless, the Manufacturer Defendants wanted to be able to spin a positive story about the use of opioids in the face of abuse.[36] After the *New York Times* published an article in February of 2001 about the abuse of OxyContin (a Purdue product), Janssen called Dr. Russell Portenoy (who later communicated this to Purdue), discussing that Janssen had "called others to try help deal with this media blitz and **protect the pain movement**."[37] Additionally, when further issues began to arise about abuse and diversion of Purdue's OxyContin, Janssen instructed its employees not use this to its competitive advantage as it would hurt the overall cause.[38] Purdue and Janssen also agreed to mutually police their sales representatives from discussing abuse during sales calls; specifically, they agreed to report on representatives who "discussed or used" "abuse and diversion reports for OxyContin, Duragesic [a Janssen product] and

[32] Exh. 28, JAN-MS-01052128; *see also* Exh. 29, JAN-MS-00456087 (touting "co-promotion" as a "Top-line Recommendation" of an "external opportunit[y]" that J&J should "invest in" "to generate revenue for 2005").
[33] Exh. 30, JAN-MS-01006283; Exh. 31, JAN-MS-00246903; Exh. 32, JAN-MS-01052181; Exh. 33, JAN-MS-01051754; Exh. 34, JAN-MS-01052165; Exh. 35, JAN-MS-00456093 (a January 3, 2001 PPT about co-promotional opportunities with Purdue states: "Reviewing how we can work together to help each company achieve maximum sales potential of existing and future products.")
[34] Exh. 36, JAN-MS-04290083, 04290087.
[35] *See supra* FN 24 (citing to guilty pleas for Purdue and Cephalon for false marketing); *see also* Exh. 37, PDD8801161604 (2/16/2001 Purdue email regarding using "advertorials" to push back against bad press, "These may be viewed by the FDA as direct to consumer advertising. . . . we will have to get up to speed quickly about how we can avoid this, as I believe that DTC advertising has to be pre-cleared.").
[36] Exh. 37, PDD8801161604.
[37] Exh. 23, PPLPC037000007677 (emphasis added).
[38] Exh. 38, JAN-MS-00307337 ("It is not our policy to advance language that would attack a competitor's product," and noting that abuse discussion can damage the whole market).

other pharmaceutical preparations" "as part of the promotion of OxyContin" so that there could be "investigation and disciplinary action if necessary."[39]

Although the seeds of cooperation had already been sown in Purdue's and Janssen's partnership, Dr. Kathleen Foley, a "Key Opinion Leader" ('KOL") and doctor with connections to both Purdue and Janssen, expressly advocated in April 2001 that the opioid manufacturers "speak with ONE VOICE."[40] She suggested to Purdue's Richard Sackler:

> **bring[] together all of the members of the pharmaceutical industry**, who have analgesic drugs out there and try **to come together as a sort of cohesive voice** recognizing that your particular drug has been recently identified in the newspapers as a drug issue. I think that there is a tightrope that you need to walk, because **you are a drug company and it would be much better if the advocacy came from outside of the drug company and even better without much in the way of support from you**. So along those lines, the kinds of things that I am thinking of is that maybe **we should call a meeting, bring together representatives from all of the companies, ideally high level representatives, like presidents or major leaders and strategize about the way to play the media issues**.[41]

Endo's co-founder, Carol Ammon, echoed this advice, stating that to "drive as much revenue" as possible, the manufacturers need to "get[] physicians" "who are thought leaders" to move the whole market towards a change in pain management.[42]

Consistent with this strategy, Cephalon and Purdue set up a luncheon in February 2003 with "pain therapy companies" with the goal of getting "to know who is interested in pain issues from the corporate side and to learn more about the American Pain Foundation's legislative agenda for 2003 and beyond. **Our goal is to build a formal or informal coalition on these issues**."[43] The American Pain Foundation ("APF") offered to "present our proposed legislative agenda" because "it is very important to share information, report on progress, etc. so that we don't inadvertently work at cross

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[39] Exh. 39, PKY182620813.
[40] Exh. 40, JAN-MS-00313199 at JAN-MS-00313202.
[41] Exh. 41, PPLPC037000008901 (emphasis added).
[42] YouTube.com, The 7 Essentials: The Endo Pharmaceuticals Story; https://www.youtube.com/watch?v=6fqFOy-bZ1k&t=13s'.
[43] Exh. 42, PPLPC022000024918 (emphasis added); Exh. 43, PPLPC021000028121 at 22; Exh. 44, PPLPC021000028122.

purposes."[44] The meeting included representatives from APF, Cephalon, Purdue, and other pharmaceutical companies.[45] In October 2003, the APF held a "Corporate Roundtable," which included Cephalon, Janssen, and Purdue.[46] Notes reflect discussions of "how to exploit decade of pain," "collaboration," "collaboration w/focus," "collab – need to coalesce a key msg," "time is now to define roles of orgs what can we each do," "industry = problem solvers," and "APF has staff – take leadership."[47]

B. The Manufacturer Defendants Put Their Plan Into Action.

Consistent with Dr. Foley's advice for the industry to speak with "one voice" by using advocates from outside the drug companies to promote the broad use of opioids for pain, the Manufacturer Defendants used a common group of third-party advocates, which included KOLs, various professional organizations, patient advocacy groups, industry organizations, and professional standards-setting organizations, all while trying to conceal the drug companies' connections to these third parties. The Manufacturer Defendants do not dispute that they silently paid millions of dollars to common third parties to promote their pro-opioid message.

In 2018, the United States Senate exposed the financial ties between several opioid manufacturers, including Purdue and Janssen, and third parties, finding that the fact that these manufacturers provided millions of dollars to third-party advocacy groups "suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging."[48] The 2018 Senate Report details how front groups such as the American Pain Society ("APS"), American Association for Pain Medicine ("AAPM"), the American Geriatric Society ("AGS"), and the American Pain Foundation ("APF"), advanced initiatives that "often echoed and amplified messages favorable

[44] *Id.*
[45] Exh. 45, PPLPC023000039492 at Exh. 46, PPLPC023000039493.
[46] TEVA_MDL_A_0550903905508891 at 903905509039-9041.
[47] Exh. 47, TEVA_MDL_A_05508891 at 93; Exh. 48, TEVA_MDL_A_05508908-8909 (emphasis in original).
[48] *Fueling an Epidemic, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security and Governmental Affairs Committee, Minority Staff Report (Feb. 2018)

to increased opioid use- and ultimately, the financial interests of opioid manufacturers."[49] According to the Senate, "these groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over prescription and misbranding."[50] Unsurprisingly, upon investigation, some groups like the American Pain Foundation immediately shut their doors, while others have declined any further money from the opioid industry.[51]

The idea behind Dr. Foley's strategy to rely on third-party advocates was that the pro-opioid messages would be more persuasive if they came from supposedly neutral third parties "outside of the drug compan[ies]."[52] Indeed, precisely because the drug companies themselves were not neutral, Purdue had observed that "we cannot conduct outreach to the media that is OxyContin specific; however, we can work to raise awareness in a non-branded format."[53] The use of third-party advocates solved this dilemma, and Dr. Foley's strategy caught on like wildfire.[54]

1. Key Opinion Leaders

Purdue, Endo, Janssen, Endo, Mallinckrodt, Teva, and Cephalon together funded and coordinated their message through a discrete number of shared "experts" (or "KOLs"). Dr. Foley was one KOL, and other prominent ones were: Russell Portenoy, David Joransson, June Dahl, Lynn

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[49] *Id.* at 1.
[50] *Id.* at 1.
[51] https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html?utm_term=.923591ad4d49; http://archive.jsonline.com/watchdog/watchdogreports/120331689.html/
[52] Exh. 41, PPLPC037000008901; *see also* Exh. 49, PPLPC012000065091 (Purdue working to raise media awareness "in an unbranded format"); Exh. 50, WIS_PPSG_000026 (PPSG acknowledging they helped passed a law in North Dakota); Exh. 51, WIS_PPSG_000036.
[53] Exh. 49, PPLPC012000065091.
[54] *See, e.g.,* Exh. 52, JAN-MS-02494558 (Influence map showing use of third-party advocates including KOLs); Exh. 53, END00033238 at END00033240 (Endo remarked that the advocacy of its third-parties would "become more focused and aligned with the direction of the company, so that Endo can take advantage of the great ties we have with professional societies, patient groups and third party advocates.")

Webster, Perry Fine, Scott Fishman, and David Haddox.[55] The Manufacturer Defendants used these shared experts to publish advocacy pieces that appeared to be scientific or medical literature to "educate" physicians and to help them with their public relations, all while promoting the Defendants' mutual pro-opioid message.[56] These KOLs also gave presentations to physicians that were, in fact, drafted by the manufacturers.[57] The KOLs propagated defendants' pro-opioid message through a seemingly neutral voice and helped to change physician prescribing behavior.[58]

For example, the defendants developed working relationships with Drs. Portenoy and Foley because of their credentials and their beliefs that opioids were prescribed too conservatively; indeed, while being funded by the pharmaceutical industry, Drs. Portenoy and Foley published a 1986 article advocating for use of opioids in treating chronic pain conditions based on a case study of only 38

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[55] *See e.g.* Foley: Purdue & Janssen, Exh. 549, Kathleen Foley Dep. (08/27/04); Exh. 54, PKY183381048 at 54-55, Purdue (Exh. 55, PKY181128168, Exh. 56, PKY180784295,); Portenoy: Endo, Janssen & Purdue (Exh. 57, 2018-02-05_RP_000221-000741), Purdue (Exh. 58, SFC00000001), Endo (Exh. 59, ENDO-CHI_LIT-00247966) Janssen (Exh. 60, JAN-MS-00000001); Joransson: Janssen (Exh. 61, WIS_Joranson_000071); Dahl: Purdue (Exh. 62, PKY180470186; Exh. 63, PKY180790274); Webster: Cephalon, Covidien, Insys, Mallinckrodt, Teva (Exh. 64, PLTF_2804_000013560), Endo (Exh. 65, CHI_002300587), Purdue (Exh. 58, SFC00000001), Mallinckrodt (Exh. 66, MNK-T1_0005823847), Janssen (Exh. 60, JAN-MS-00000001); Fine: Purdue (Exh. 58, SFC00000001), Endo (Exh. 59, ENDO-CHI_LIT-00247966), Janssen (Exh. 60, JAN-MS-00000001); Fishman: Purdue (Exh. 58, SFC00000001; Exh. 67, PPLP003477086), Endo (Exh. 59, ENDO-CHI_LIT-00247966), Janssen (Exh. 60, JAN-MS-00000001); Haddox: Purdue (Exh. 68, PPLPC013000032704; Exh. 69, PDD8801293266; Exh. 70, PDD1701853088; Exh. 71, PKY181058664; Exh. 72, PDD1701260996; Exh. 73, PKY180481336; Exh. 74, PDD1701553475; Exh. 75, PKY180770966). After becoming a KOL and paid advocate for the Conspirators, David Haddox was quickly hired by Purdue to help master-mind and coordinate the scheme from inside the company. Exh. 68, PPLPC013000032704; Exh. 76, PDD8801293266; Exh. 70, PDD1701853088; Exh. 71, PKY181058664; Exh. 72, PDD1701260996; Exh. 73, PKY180481336; Exh. 74, PDD1701553475; Exh. 75, PKY180770966. *See also* Exh. 77, PPLPC018000050847 (Purdue noted that the Janssen website has an introductory video that uses one of Purdue's thought leaders); *Id.* (Purdue noting that Janssen's NPEC speakers "spoke for us at regional and national meetings"); *see* Exh. 78, PKY181221797 1997 APS/AAPM Consensus statement drafted by Haddox, Portenoy, Carr, Angarola, Joransson, Carr and Payne).

[56] Portenoy R and Foley K. Chronic use of opioid analgesics in non-malignant pain: Report of 38 cases. Pain 1986; 25:171-186; Exh. 79, APS-MDL00000005 (AAPM and APS Consensus Statement - Use of Opioids for the Treatment of Chronic Pain); Exh. 80, ABT-MDL-KY-0043299 (JCAHO Pain Standards for 2001 at p. 13 and 1998 FSMB Model Guidelines for the Use of Controlled Substances for the Treatment of Pain at p. 25); Model Policy for the Use of Controlled Substances for the Treatment of Pain (2004); Scott Fishman, FSMB Responsible Opioid Prescribing: A Clinician's Guide (2007); Managing Persistent Pain in Older Persons – American Geriatric Society (1998); Management of Persistent Pain in Older Persons-American Geriatric Society (2002); The Pharmacological Management of Pain in Older Persons (2009).

[57] *See* APS, AAPM and AGS discussion below; *see also* Exh. 81, JAN-MS-00306713 Janssen's NPEC co-chaired by Dr. Russell Portenoy (KOL and former APS President), Dr. Richard Payne (KOL), with numerous other doctors and a JACHO representative sitting on its executive committee and peer review committee.

[58] *See supra*, footnote 56.

patients.[59] Dr. Portenoy testified that he was a paid speaker or advisor to "many pharmaceutical companies who sold opioid products," including Cephalon, Endo, Janssen, and Purdue.[60] Tellingly, Dr. Portenoy acknowledges that this type of "education" was designed to, and did, influence physician decision making.[61] And he now admits that he "gave innumerable lectures in the late 1980s and 1990s about addiction that weren't true," and that "[d]ata about the effectiveness of opioids does not exist."[62] Portenoy believes the way that the Manufacturer Defendants used his work, and the work of others, to influence physician decision-making was one of the contributing factors to the opioid crisis.[63]

Defendants' shared KOLs traveled the country as paid speakers to deliver the Defendants' message. These paid speakers, who received funding from multiple Defendants, were routinely handed slide decks and presentation materials from the Defendants that they were expected to deliver without modification.[64]

The Manufacturer Defendants all supported their shared KOLs' messages through substantial funding. For example, from the 1980s through 2014, Purdue and Janssen put Drs. Portenoy and Foley on the pay roll and also began pouring millions of dollars into the institutions where they practiced medicine.[65] Endo, Purdue, and Cephalon all funded and used Dr. Webster as a KOL, paying him millions of dollars to promote their pro-opioid message (Cephalon alone gave Dr. Webster nearly

[59] See Russell K. Portenoy & Kathleen M. Foley, Chronic Use Of Opioid Analgesics In Non-Malignant Pain: Report Of 38 Cases, Pain 25.2, 171-186 (1986); Exh. 82, Foley Dep., PKY183381048 at 7-8. *See also* Perri Rep., Dkt. # 2000-19, at Schedule 17; See Russell Portenoy Dep. (01/24/19), Dkt. # 1969-11 at 46:10-20; Exh. 83, PPLPC025000005629.
[60] Portenoy Dep., Dkt. # 1969-11 at 14:17-15:13.
[61] Portenoy Dep., Dkt. # 1969-11 at 43:8-20.
[62] Thomas Catan & Evan Perez, A Pain-Drug Champion Has Second Thoughts, Wall. St. J. (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[63] Portenoy Dep., Dkt. # 1969-11 at 44:11-45:6; 43:22-44:8.
[64] Exh. 671 (Melanie Rosenblatt Dep. (05/31/19) at 207:23-209:9); Exh. 672 (Michael Miller Dep. (06/04/19) at 186:1-188:17).
[65] *See* (Exh. 88, PPLPC017000604922; *see also* Foley: Purdue & Janssen, Exh. 82, Foley Dep., PKY183381048 at 7:22-8:6), Purdue (Exh. 84, PKY181128168; Exh. 56, PKY180784295); Portenoy Dep., Dkt. # 1969-11 at 46:10-20; Endo, Janssen & Purdue (Exh. 57, 2018-02-05_RP_000221-000741); Purdue (Exh. 58, SFC00000001); Endo (Exh. 59, ENDO-CHI_LIT-00247966) Janssen (Exh. 60, JAN-MS-00000001); Portenoy Dep., Dkt. # 1969-11 at 46:10-20.

$2 million dollars).[66] Purdue, Endo, and Janssen also funded and coordinated their message through Dr. Fishman.[67]

2. Professional and Patient Advocacy Organizations ("Front Groups")

In addition to KOLs, the Manufacturer Defendants used numerous common organizations that were tied to the so-called "pain movement" to front their message, including the American Pain Foundation, the American Pain Society, the University of Wisconsin Pain and Policy Studies Group, the American Academy of Pain Medicine, and the American Geriatric Society ("front groups").[68] Richard Sackler of Purdue put it succinctly in 2001: "Our goal is to bind these organizations more

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[66] Cephalon, Covidien, Insys, Mallinckrodt, Teva (PLTF_2804_000013560); Endo (CHI_002300587); Purdue (Exh. 58, SFC00000001); Mallinckrodt (Exh. 66, MNK-T1_0005823847); Janssen (Exh. 60, JAN-MS-00000001); Fishman: Purdue (Exh. 58, SFC00000001; Exh. 67, PPLP003477086), Endo (Exh. 59, ENDO-CHI_LIT-00247966); Janssen (Exh. 60, JAN-MS-00000001).

[67] Fishman: Purdue (Exh. 58, SFC00000001; Exh. 67, PPLP003477086), Endo (Exh. 59, ENDO-CHI_LIT-00247966), Janssen (Exh. 60, JAN-MS-00000001).

[68] *See* Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups (Report 2) (https://www.hsdl.org/?abstract&did=808171) (payments made by Purdue, Janssen, and Insys since January 2012 to AAPM, APF, APS); *see also* APF payments (Endo: Exh. 85, END00735356; Janssen: Exh. 86, JAN-MS-03089430; Exh. 60, JAN-MS-00000001; Exh. 87, CHI_001715794 at 96, 98 (Ortho-McNeil gave APF first $250,000); Purdue: Exh. 88, PPLPC017000604922); APS payments (Endo, Purdue, Teva, Cephalon, Actavis, Allergan, Janssen, and Mallinckrodt: Exh. 89, CHI_001978630; Exh. 90, APS-MDL00000001; Insys: Exh. 91, INSYS-MDL-003350902; Janssen: Exh. 86, JAN-MS-03089430; Purdue: Exh. 88, PPLPC017000604922); AGS payments (Endo: Exh. 92, ENDO-OPIOID_MDL-01445020; Janssen: Exh. 86, JAN-MS-03089430; Exh. 93, JAN-MS-00313716; Exh. 94, JAN-MS-00247231; Exh. 95, JAN-MS-00306263; Exh. 96, JAN-MS-00306275; Exh. 97, JAN-MS-00308836, Exh. 98, JAN-MS-00474421; Exh. 99, JAN-MS-00474423; Exh. 100, JAN-MS-00395592; Exh. 101, JAN-MS-00395594; Exh. 102, JAN-MS-00395596; Exh. 103, JAN-MS-00395599; Exh. 104, JAN-MS-00264548; Exh. 105, JAN-MS-00395611; Exh. 106, JAN-MS-00395613; Exh. 107, JAN-MS-00395614; Exh. 108, JAN-MS-00262912; Exh. 109, JAN-MS-00395603; Exh. 110, JAN-MS-00395630; Exh. 111, JAN-MS-00264370; Exh. 112, JAN-MS-00409782; Purdue: Exh. 88, PPLPC017000604922); UW Pain and Policy payments (Allergan, Endo, Purdue, and Janssen: Exh. 113, WIS_PPSG_005251; CHI_00443601; Janssen: Exh. 86, JAN-MS-03089430; Purdue: Exh. 88, PPLPC017000604922); AAPM payments (Endo: Exh. 114, ENDO-OPIOID_MDL-01444991; Exh. 115, ENDO-OPIOID_MDL-01444993; Exh. 116, ENDO-OPIOID_MDL-04669404; Exh. 117, ENDO-OPIOID_MDL-04669418; Exh. 118, ENDO-OPIOID_MDL-04669526; Exh. 119, ENDO-OPIOID_MDL-04669540; Exh. 120, ENDO-OPIOID_MDL-04754767; Exh. 121, EPI000649269; Exh. 122, ENDO-OPIOID_MDL-01445157; Exh. 123, EPI000664622; Exh. 124, ENDO-OPIOID_MDL-01445159; Insys: Exh. 91, INSYS-MDL-003350902; Exh. 125, INSYS-MDL-010473678; Exh. 126, INSYS-MDL-010477470; Exh. 127, INSYS-MDL-010477473; Exh. 128, INSYS-MDL-005393278; Exh. 129, INSYS-MDL-006047762; Exh. 130, INSYS-MDL-010471732; Exh. 131, INSYS-MDL-010477468; Janssen: Exh. 86, JAN-MS-03089430; Exh. 93, JAN-MS-00313716; Exh. 132, JAN-MS-00314059; Exh. 95, JAN-MS-00306263; Exh. 133, JAN-MS-00315325; Exh. 134, JAN-MS-00828205; Exh. 135, JAN-MS-00408422; Exh. 136, JAN-MS-00928065; Exh. 137, JAN-MS-00928067; Exh. 138, JAN-MS-00350962; Exh. 139, JAN-MS-00393409; Exh. 140, JAN-MS-00410890; Exh. 141, JAN-MS-01239356; Exh. 142, JAN-MS-00323434; Exh. 143, JAN-MS-00323859; Exh. 144, JAN-MS-00350802; Exh. 145, JAN-MS-00325962; Exh. 146, JAN-MS-00918396; Exh. 147, JAN-MS-00949290; Exh. 148, JAN-MS-01151875; Exh. 149, JAN-MS-00427861; Exh. 150, JAN-MS-02659095; Purdue: Exh. 88, PPLPC017000604922); *see also Fueling and Epidemic, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security and Governmental Affairs Committee, Minority Staff Report (Feb. 2018)

closely to us than heretofore, but also to align them with our expanded mission [expanding the market for opioids] and to see that **the fate of our product(s) are [sic] inextricably bound up with the trajectory of the pain movement**."[69]

For decades, the Manufacturer Defendants did just that, working together with these common professional organizations, associations, and patient advocacy groups. The Manufacturer Defendants funded these organizations, paid advocates who staffed their boards, authored advocacy pieces that were published by the organizations (without attribution to the manufacturers), and then cited to these "neutral" pieces in their marketing. Purdue's Robin Hogen stated, "[i]f [these front groups] want our bucks (and they honestly cannot survive without industry support) they are going to have to learn to live with 'industry' reps on their board. I don't think they can expect huge grants without some say in governance."[70]

The Manufacturer Defendants shared responsibility for financially supporting the front groups. Purdue, Janssen, Endo, Cephalon, Mallinckrodt, and Teva enlisted these common organizations in "the mission," funneling money (often in amounts that were a substantial part of the groups' annual budgets) to them for over a decade, and played a key role in directing their actions through that money and through KOLs (or the Manufacturer Defendants' employees), who were paid to assume leadership roles in those organizations.[71] Purdue alone spent $115 million funding outside organizations from 2002 to 2015, including millions of dollars to these critical front groups.[72]

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[69] PPLPC045000004928 at 29 (emphasis added).
[70] PPLPC02500001258.
[71] See Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups (Report 2) (https://www.hsdl.org/?abstract&did=808171); Portenoy: Endo, Janssen & Purdue (2018-02-05_RP_000221-000741), Purdue (Exh. 58, SFC00000001), Endo (Exh. 59, ENDO-CHI_LIT-00247966) Janssen (Exh. 60, JAN-MS-00000001); Webster: Cephalon, Covidien, Insys, Mallinckrodt, Teva (PLTF_2804_000013560), Endo (CHI_002300587), Purdue (Exh. 58, SFC00000001), Mallinckrodt (MNK-T1_0005823847), Janssen (Exh. 60, JAN-MS-00000001); Fine: Purdue (Exh. 58, SFC00000001), Endo (Exh. 59, ENDO-CHI_LIT-00247966), Janssen (Exh. 60, JAN-MS-00000001); Fishman: Purdue (Exh. 58, SFC00000001; Exh. 67, PPLP003477086; Exh. 59, ENDO-CHI_LIT-00247966; Janssen (Exh. 60, JAN-MS-00000001).
[72] Exh. 88, PPLPC017000604922; Other Defendants did the same, *see* Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups (Report 2) (https://www.hsdl.org/?abstract&did=808171) (payments made by Purdue, Janssen, and Insys since January 2012 to

The University of Wisconsin Pain and Policy Studies Group ("PPSG"), headed by David Joranssen and Aaron Gilson, was one key front group, which "work[ed] to identify and address regulatory barriers to pain management…. and improved availability of opioid analgesics."[73] The Manufacturer Defendants contributed millions of dollars to the PPSG; money that went undisclosed from the late 1990s until a journalistic expose was written about the group's ties to the opioid industry in 2011.[74] From 2005-2008, Purdue Pharma alone paid PPSG "$100,000 annually for the US program

AAPM, APF, APS); *see also* APF payments (Endo: Exh. 85, END00735356; Janssen: Exh. 86, JAN-MS-03089430; Exh. 152, JAN-MS-00787662; Purdue: Exh. 88, PPLPC017000604922); APS payments (Endo, Purdue, Teva, Cephalon, Actavis, Allergan, Janssen, and Mallinckrodt: Exh. 89, CHI_001978630; Exh. 90, APS-MDL00000001; Insys: Exh. 91, INSYS-MDL-003350902; Janssen: Exh. 86, JAN-MS-03089430; Purdue: Exh. 88, PPLPC017000604922); AGS payments (Endo: Exh. 92, ENDO-OPIOID_MDL-01445020; Janssen: Exh. 86, JAN-MS-03089430 Exh. 93, JAN-MS-00313716; Exh. 94, JAN-MS-00247231; Exh. 95, JAN-MS-00306263; Exh. 96, JAN-MS-00306275; Exh. 97, JAN-MS-00308836, Exh. 98, JAN-MS-00474421; Exh. 99, JAN-MS-00474423; Exh. 100, JAN-MS-00395592; Exh. 101, JAN-MS-00395594; Exh. 102, JAN-MS-00395596; Exh. 103, JAN-MS-00395599; Exh. 104, JAN-MS-00264548; Exh. 105, JAN-MS-00395611; J Exh. 106, JAN-MS-00395613; Exh. 107, JAN-MS-00395614; Exh. 108, JAN-MS-00262912; Exh. 109, JAN-MS-00395603; Exh. 110, JAN-MS-00395630; Exh. 111, JAN-MS-00264370; Exh. 112, JAN-MS-00409782; Purdue: Exh. 88, PPLPC017000604922); UW Pain and Policy payments (Allergan, Endo, Purdue, and Janssen: Exh. 113, WIS_PPSG_005251; Janssen: Exh. 86, JAN-MS-03089430; Purdue: Exh. 88, PPLPC017000604922); AAPM payments (Endo: Exh. 114, ENDO-OPIOID_MDL-01444991; Exh. 115, ENDO-OPIOID_MDL-01444993; Exh. 116, ENDO-OPIOID_MDL-04669404; Exh. 117, ENDO-OPIOID_MDL-04669418; Exh. 118, ENDO-OPIOID_MDL-04669526; Exh. 119, ENDO-OPIOID_MDL-04669540; Exh. 120, ENDO-OPIOID_MDL-04754767; Exh. 121, EPI000649269; Exh. 122, ENDO-OPIOID_MDL-01445157; Exh. 123, EPI000664622; Exh. 124, ENDO-OPIOID_MDL-01445159; Insys: Exh. 91, INSYS-MDL-003350902; Exh. 125, INSYS-MDL-010473678; Exh. 126, INSYS-MDL-010477470; Exh. 127, INSYS-MDL-010477473; Exh. 128, INSYS-MDL-005393278; Exh. 129, INSYS-MDL-006047762; Exh. 130, INSYS-MDL-010471732; Exh. 131, INSYS-MDL-010477468; Janssen: Exh. 86, JAN-MS-03089430, Exh. 93, JAN-MS-00313716; Exh. 132, JAN-MS-00314059; Exh. 95, JAN-MS-00306263; Exh. 133, JAN-MS-00315325; Exh. 134, JAN-MS-00828205; Exh. 135, JAN-MS-00408422; Exh. 136, JAN-MS-00928065; Exh. 137, JAN-MS-00928067; Exh. 138, JAN-MS-00350962; Exh. 139, JAN-MS-00393409; Exh. 140, JAN-MS-00410890; Exh. 141, JAN-MS-01239356; Exh. 142, JAN-MS-00323434; Exh. 143, JAN-MS-00323859; Exh. 144, JAN-MS-00350802; Exh. 145, JAN-MS-00325962; Exh. 146, JAN-MS-00918396; Exh. 147, JAN-MS-00949290; Exh. 148, JAN-MS-01151875; Exh. 149, JAN-MS-00427861; Exh. 150, JAN-MS-02659095; Purdue: Exh. 88, PPLPC017000604922).)

[73] Exh. 151, PDD1701481531 at 32.

[74] *See* Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups (Report 2) (https://www.hsdl.org/?abstract&did=808171) (payments made by Purdue, Janssen, and Insys since January 2012 to AAPM, APF, APS); *see also* APF payments (Endo: Exh. 85, END00735356; Janssen: Exh. 86, JAN-MS-03089430; Exh. 152, JAN-MS-00787662; Purdue: Exh. 88, PPLPC017000604922); APS payments (Endo, Purdue, Teva, Cephalon, Actavis, Allergan, Janssen, and Mallinckrodt: Exh. 89, CHI_001978630; Exh. 90, APS-MDL00000001; Insys: Exh. 91, INSYS-MDL-003350902; Janssen: Exh. 86, JAN-MS-03089430; Purdue: Exh. 88, PPLPC017000604922); AGS payments (Endo: Exh. 92, ENDO-OPIOID_MDL-01445020; Janssen: Exh. 86, JAN-MS-03089430; Exh. 93, JAN-MS-00313716; Exh. 94, JAN-MS-00247231; Exh. 95, JAN-MS-00306263; Exh. 96, JAN-MS-00306275; Exh. 97, JAN-MS-00308836, Exh. 98, JAN-MS-00474421; Exh. 99, JAN-MS-00474423; Exh. 100, JAN-MS-00395592; Exh. 101, JAN-MS-00395594; Exh. 102, JAN-MS-00395596; Exh. 103, JAN-MS-00395599; Exh. 104, JAN-MS-00264548; Exh. 105, JAN-MS-00395611; Exh. 106, JAN-MS-00395613; Exh. 107, JAN-MS-00395614; Exh. 108, JAN-MS-00262912; Exh. 109, JAN-MS-00395603; Exh. 110, JAN-MS-00395630; Exh. 111, JAN-MS-00264370; Exh. 112, JAN-MS-00409782; Purdue: Exh. 88, PPLPC017000604922); UW Pain and Policy payments (Allergan, Endo, Purdue, and Janssen: Exh. 113, WIS_PPSG_005251; Janssen: Exh. 86, JAN-MS-03089430; Purdue: Exh. 88, PPLPC017000604922); AAPM payments (Endo: Exh. 114, ENDO-OPIOID_MDL-01444991; Exh. 115, ENDO-OPIOID_MDL-01444993; Exh. 116, ENDO-

and $175,000 annually for the international program."[75] But the appearance of the front group's independence (and non-disclosure of these contributions) was critical to its partnership (and funding) with the Manufacturer Defendants, as reflected by the response of the PPSG's assistant director after someone asked about the group's influence on pending industry legislation: "I'm impressed that you could detect our finger prints... I'll wear gloves next time."[76]

Janssen, Purdue, Endo, Mallinckrodt, and Teva also worked together through the American Pain Society ("APS"), to promote their mutual message and dramatically expand the market for prescription opioids.[77] Starting in the mid-1990s, Manufacturer Defendants, including Purdue and Janssen, substantially contributed to APS, often forming large chunks of the organization's operating budget.[78] The Manufacturer Defendants' employees or paid advocates, including David Haddox, David Joransson, Robert Angarola (a Johnson & Johnson attorney), David Carr, Richard Payne and Russell Portenoy, generated an initial "consensus,"[79] stating that opioids were safe and could be widely used for chronic pain conditions, which was then issued by APS.[80] The Manufacturer Defendants and

OPIOID_MDL-04669404; Exh. 117, ENDO-OPIOID_MDL-04669418; Exh. 118, ENDO-OPIOID_MDL-04669526; Exh. 119, ENDO-OPIOID_MDL-04669540; Exh. 120, ENDO-OPIOID_MDL-04754767; Exh. 121, EPI000649269; Exh. 122, ENDO-OPIOID_MDL-01445157; Exh. 123, EPI000664622; Exh. 124, ENDO-OPIOID_MDL-01445159; Insys: Exh. 91, INSYS-MDL-003350902; Exh. 125, INSYS-MDL-010473678; Exh. 126, INSYS-MDL-010477470; Exh. 127, INSYS-MDL-010477473; Exh. 128, INSYS-MDL-005393278; Exh. 129, INSYS-MDL-006047762; Exh. 130, INSYS-MDL-010471732; Exh. 131, INSYS-MDL-010477468; Janssen: Exh. 86, JAN-MS-03089430, Exh. 93, JAN-MS-00313716; Exh. 132, JAN-MS-00314059; Exh. 95, JAN-MS-00306263; Exh. 133, JAN-MS-00315325; Exh. 134, JAN-MS-00828205; Exh. 135, JAN-MS-00408422; Exh. 136, JAN-MS-00928065; Exh. 137, JAN-MS-00928067; Exh. 138, JAN-MS-00350962; Exh. 139, JAN-MS-00393409; Exh. 140, JAN-MS-00410890; Exh. 141, JAN-MS-01239356; Exh. 142, JAN-MS-00323434; Exh. 143, JAN-MS-00323859; Exh. 144, JAN-MS-00350802; Exh. 145, JAN-MS-00325962; Exh. 146, JAN-MS-00918396; Exh. 147, JAN-MS-00949290; Exh. 148, JAN-MS-01151875; Exh. 149, JAN-MS-00427861; Exh. 150, JAN-MS-02659095; Purdue: Exh. 88, PPLPC017000604922; *see also* http://archive.jsonline.com/watchdog/watchdogreports/119130114.html.

[75] Exh. 153, WIS_PPSG_008286.

[76] Exh. 51, WIS_PPSG_000036.

[77] Exh. 58, SFC00000001 (Purdue); Exh. 60, JAN-MS-00000001 (Janssen/J&J); Exh. 59, ENDO-CHI_LIT-00247966 (Endo); Exh. 90, APS-MDL00000001 (Teva; Mallinckrodt).

[78] Exh. 58, SFC00000001 (Purdue); Exh. 60, JAN-MS-00000001 (Janssen/J&J).

[79] AAPM & APS, *The Use of Opioids for the Treatment of Chronic Pain: A consensus statement from the American Academy of Pain Medicine and the American Pain Society*, 6 J. of Pain 1, 77-79 (1997)

[80] Exh. 154, PKY181731797.

their paid advocates and employees were not disclosed as authors, nor were their financial connections to the organizations disclosed.[81]

Purdue, Janssen, Endo, Cephalon, and Actavis used the American Academy of Pain Medicine ("AAPM") as another front group and provided substantial funding to it from 1997 until at least 2012, when the organization was investigated by the U.S. Senate. One recent AAPM President, Dr. Charles Argoff, received more than $600,000 from opioids manufacturers between 2013 to 2016.[82]

The American Pain Foundation (APF) was a patient advocacy group that was largely funded by the Manufacturer Defendants.[83] Endo, Purdue, Cephalon, and Janssen contributed millions of dollars to APF from its founding in 1997 until it closed its doors in 2012, upon being investigated by the Senate.[84] Between 2007 and 2012, APF received more than $10 million from the Manufacturer Defendants, including Endo, who gave more than $5 million, and Purdue who provided $1.7 million.[85] APF developed patient testimonials, such as the 2009 "Exit Wounds," where pain patients talked about the benefits of opioids in what appeared to be an unbiased testimonial.[86]

Purdue, Endo, and Janssen also contributed to the American Geriatric Society ("AGS"). After that funding began—Purdue and Janssen began funding around 1997—the AGS published Guidelines

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[81] *Id.*

[82] *See, Fueling an Epidemic*, at 10 and n.45.

[83] Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups (Report 2) (https://www.hsdl.org/?abstract&did=808171); Exh. 58, SFC0000001; Exh. 156, MNK-T1_0008005740; Exh. 684, JJ-SFC-00000001; Exh. 157, END00041232 at 8; Exh. 158, PPLP003477687; Exh. 159, PKY180772092; Exh. 160, ENDO-OPIOID_MDL-01610298; Exh. 161, PPLPC020000005715; Exh. 162, PDD8801291781; Exh. 163, PKY182717470; Exh. 164, JAN-MS-00312347; Exh. 89, CHI_001978630.

[84] *See* Exh. 58, SFC00000001; Exh. 156, MNK-T1_0008005740; Exh. 157, END00041232 at 8; Exh. 158, PPLP003477687; Exh. 159, PKY180772092; Exh. 160, ENDO-OPIOID_MDL-01610298; Exh. 161, PPLPC020000005715; Exh. 162, PDD8801291781; Exh. 163, PKY182717470; Exh. 164, JAN-MS-00312347; Exh. 89, CHI_001978630.

[85] Exh. 58, SFC00000001; Exh. 89, CHI_001978630.

[86] Exh. 685, JAN-MS-00324305, Exh. 686, JAN-MS-00927589, Exh. 687, JAN-MS-00932379, Exh. 688, JAN-MS-00938504; Exh. 689, JAN-MS-00925643; Exh. 690, PPLP004081148; Exh. 691, ENDO-OPIOID_MDL-01412623.

that recommended expansive use of opioids and argued that addiction risks from opioids were very low.[87]

In addition to the Manufacturer Defendants' substantial funding to these front groups to promote pro-opioid messages, the Manufacturer Defendants placed their paid advocates or employees in leadership roles, where these individuals could author or influence the front groups' policies, guidelines, and standards to further promote increased use of opioids. For example, KOLs Fine, Portenoy, Fishman, and Webster each served as President of the AAPM.[88] Dr. Fishman, who was President of AAPM, and board member of APF, commented that AAPM was "at the forefront" of distributing the message that "the risks of addiction are...small and can be managed."[89] He also authored a book, "Responsible Opioid Prescribing," which the Manufacturer Defendants funded and heavily relied upon to allay concerns about opioid abuse.

Similarly, Dr. Haddox played an active part in the AAPM and in the content of its advocacy. Similarly, Dr. Haddox played an active part in the AAPM and in the content of its advocacy.[90] Dr. Haddox also played an influential role at APF, where he edited a patient guide—the Pain Action Guide—and was thereby able to craft its language on addiction, stating the "notion of drugs being 'addictive' is a flawed one and *shouldn't be propagated by* an organization like the APF."[91] The Manufacturer Defendants paid to be on the "corporate relations counsel," of the AAPM; membership

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[87] *See*, The Management of Persistent Pain in Older Persons, Journal of the American Geriatrics Society 50.6 Suppl. (2002); The Pharmacological Management of Pain in Older Persons published by the American Geriatric Society, Exh. 155, CHC-00068828 (2009).

[88] *See*, Past Presidents, American Academy of Pain Medicine, available at https://painmed.org/about/board/council-of-past-presidents, last accessed on July 30, 2019.

[89] Paula Moyer, The Current State of Pain Management, MedScape (2005), https:www.medscape.org/viewarticle/500829.

[90] Exh. 692, Elizabeth Tatum Dep. (12/11/18), at 54:11-14; 135:10-14 (former AAPM employee); AAPM & APS, *The Use of Opioids for the Treatment of Chronic Pain: A consensus statement from the American Academy of Pain Medicine and the American Pain Society*, 6 J. of Pain 1, 77-79 (1997).

[91] Alan Must Dep. (3/14/19), Dkt. #1968-13 at Ex. 10; Must Dep., Dkt. #1968-13 at 78-83. Purdue had provided APF $600,000 in funding during the same timeframe that the APF published and distributed the Pain Action Guide. Must Dep. at 82.

options came with increasing levels of control and access to AAPM, its resources, its employees, and leadership.[92]

3. Industry Organization: Pain Care Forum

One of the most critical of the Manufacturer Defendants' advocates was the Pain Care Forum ("PCF"), which was not a third-party, but a forum run by the Manufacturer Defendants themselves to facilitate direct coordination amongst them. Purdue employee, Burt Rosen, and others organized the Pain Care Forum in 2005.[93] Purdue, Cephalon, Johnson & Johnson, and APF were among its early participants,[94] but eventually the PCF included all of the Manufacturer Defendants, the Distributors' association (the HDA), other trade associations, numerous front groups, the FSMB, and PhRMA.[95] The group was a forum for industry to meet and discuss issues related to the supply of prescription opioids, and to coordinate media campaigns that had the appearance of coming from a "neutral" third-party. The Manufacturer Defendants used the PCF to coordinate their desired messaging with all of their front groups.

Purdue employee Burt Rosen explained the PCF's purpose: "I think this could fill the vacuum of leadership in the community at large, and provide for some **unified direction** on issues of importance to the pain community."[96] The Pain Care Forum meetings were not public[97] and no

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[92] *See*, Corporate Relations Council, American Academy of Pain Medicine, available at https://painmed.org/about/corporate-support/corporate-relations-council, last accessed on July 30, 2019; *see also*, Corporate Relations Council: Striving for Better Patient Care, American Academy of Pain Medicine, available at https://painmed.org/uploads/about/aapm-corporate-relations-council-brochure.pdf, last accessed on July 30, 2019.

[93] Rosen Dep., Dkt. # 1970-10 at 60:1-3.

[94] Exh. 165, PPLPC024000125469; PPLPC021000071400; PPLPC021000222248.

[95] Rosen Dep., Dkt. # 1970-10 at 59:23-60:13; Exh. 1, PPLP004272094 (List of "Pain Care Forum Participating Organizations" includes manufacturer defendants Allergan, Teva (Cephalon), Endo, Johnson & Johnson, and Purdue Pharma; the Healthcare Distribution Management Association (HDA) and National Association of Chain Drug Stores (NACDS) and front groups such as the American Pain Society, American Academy of Pain Medicine, American Association for Pain Medicine, American Pain Foundation, Pain & Policy Studies Group, and Federation of State Medical Boards). Mallinckrodt was a member. *See* Rosen Dep., Dkt. # 1970-10 at 69:23-70:1.

[96] Exh. 165, PPLPC024000125469 (emphasis added); *see also* Exh. 166, PPLPC031000222246 at PPLPC031000222247 ("Where possible, we hope to coordinate and focus commitments to actions regarding public policy issues that affect the treatment of pain.").

[97] Rosen Dep., Dkt. # 1970-10 at 72:1-3.

minutes were officially taken.[98] There is no PCF website[99] or public list of members, no public announcement of meetings or public agendas,[100] no official transcripts or record of their discussions,[101] and no antitrust counsel attended these meetings – even though many members were direct competitors.[102] To those outside the industry, therefore, the PCF appeared to be simply another patient advocacy group or professional organization.[103]

The PCF's agenda was to further the goals of the Manufacturer Defendants by facilitating coordination amongst the manufacturer members and the rest of industry to oppose any restrictions on the supply, sales, or use of prescription opioids.[104] The PCF could take positions and coordinate on issues with other members.[105] This was big business; although Burt Rosen denied that the PCF itself had a budget or hired lobbyists,[106] public information indicates that, between 2006 and 2015, the Pain Care Forum's members spent nearly $900 million to influence government.[107]

There are several key examples of how the Pain Care Forum facilitated coordination among the Manufacturer Defendants.

a. REMS

The Manufacturer Defendants used the Pain Care Forum to "coordinate strategy and [] to address the FDAs REMS proposals."[108] In 2007, Congress gave the FDA authority to require Risk Evaluation and Mitigation Strategies ("REMS") to heighten various safety measures for drugs.[109]

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[98] Rosen Dep., Dkt. # 1970-10 at 72:18-21.
[99] Rosen Dep., Dkt. # 1970-10 at 71:23-24.
[100] Rosen Dep., Dkt. # 1970-10 at 72:13-15.
[101] Rosen Dep., Dkt. # 1970-10 at 77:6-15.
[102] Rosen Dep., Dkt. # 1970-10 at 237:17-24.
[103] Exh. 167, PPLP004051877 (Explaining need to keep PCF media and congressional campaign a secret); Exh. 4, PPLP004051807 (On a PCF media program to oppose measures to adopt more restrictive REMS, "this program should be driven by the not-for-profit community, potentially with multiple industry sponsors")
[104] *See e.g.* Rosen Dep., Dkt. # 1970-10 at 191; Exh. 168, PPLPC019000247613; Exh. 4, PPLP004051807.
[105] Rosen Dep., Dkt. # 1970-10 at 160:7-13.
[106] Rosen Dep., Dkt. # 1970-10 at 60:17-18, 61:9-10.
[107] http://data.ap.org/projects/2016/cpi_ap_opioids/indexcpiap.html
[108] Rosen Dep., Dkt. # 1970-10 at 191:1-9.
[109] Exh. 169, PPLPC051000064077 (Food and Drug Administration Amendments Act of 2007).

Around 2008, the FDA was contemplating a REMS program for long-acting and extended-release (LA/ER) opioids,[110] and asked the Manufacturer Defendants to form an Industry Working Group to coordinate their position.[111] The FDA Industry Working Group meetings, however, were on the record and, because the Manufacturing Defendants are direct competitors, were attended by antitrust counsel.[112] Neither the distributors nor the various front groups were invited by FDA to participate.[113] The PCF, therefore, created its own REMS Task Force that included these groups.[114]

Defendants used the PCF to present what, from the FDA's perspective, looked like a "grass roots" concern by patients and health care providers.[115] The PCF Task Force reviewed a draft letter to the FDA recommending mandatory physician and pharmacist training and certification requirements as a prerequisite to prescribing and dispensing LA/ER opioids.[116] The PCF, working with the HDA, deleted that part, stating "we shouldn't mention a 'certification' requirement for

[110] Rosen Dep., Dkt. # 1970-10 at 191:1-9.
[111] Exh. 170, EPI000066634 (IWG Submission to FDA Docket detailing FDA's request to form IWG); Exh. 171, EPI001059511; *See also* Rosen Dep., Dkt. # 1970-10 Exh. 27 at 10 (internal IWG REMS analysis stating that the FDA's goal for REMS to "Reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of long-acting and extended-release opioids while maintaining patient access to these medications" "*differs* from the goal proposed by the Industry Working Group (IWG)."
[112] Exh. 172, PPLP004299456 (Meeting minutes of first IWG meeting); Rosen Dep., Dkt. # 1970-10 at 237:12-16 (IWG meetings were attended by antitrust counsel).
[113] Rosen Dep., Dkt. # 1970-10 at. Exh. 27 at 6 (IWG presentation listing IWG members).
[114] Exh. 171, EPI001059511 (2008 Will Rowe email RE: PCF REMS Task Force with recipients from organizations including APHA, PPSG, Allergan, Endo, Purdue, J&J, NHPCO, Cephalon, HDMA, and APF); Rosen Dep., Dkt. # 1970-10 at Exh. 23, Exh. 24, and Exh. 25 (PCF emails re REMS Task Force, including email from HDMA commenting on proposed letter to FDA).
[115] See Rosen Dep., Dkt. # 1970-10 at Exh. 27 a 12 (listing Pain Care Forum members for FDA but omitting any of the IWG members or the HDMA); *id.* at 28 (telling the FDA that the "PCF, generally, agreed with the IWG draft REMS," but omitting any mention that the manufacturers and HDMA had leading roles in formulating the PCF's position).
[116] Rosen Dep., Dkt. # 1970-10 at 198-204, 206-210; Rosen Dep., Dkt. # 1970-10 at Exh. 23 (draft letter to FDA); Rosen Dep., Dkt. # 1970-10 at Exh. 23 at 3 (earlier draft with identical language); Rosen Dep., Dkt. # 1970-10 at Exh. 24 at 5 (draft letter stating, "we *encourage* FDA to implement targeted prescriber and pharmacist education with appropriate confirmation requirements as a prerequisite to prescribing and dispensing these products.") (emphasis added); see e.g. Exh. 173, PPLP004052907 (Will Rowe email acknowledging "We hope to develop a letter that is amenable to all the principal stakeholders. . .".

physicians (or anyone else for that matter.)"[117] The final letter to the FDA did not mention the HDA's or the PCF's role in drafting the letter.[118]

The PCF also prepared form "recommendations" for its front group members to use to submit comments to the FDA on REMS.[119] When one PCF member raised concern that the FDA "may feel it was rather duplicitous of the [industry members] to meet with [the FDA commissioner] and not mention that these were in the works," he was told, "It's the way things work" and there was a "need to keep silent on the congressional and media strategies."[120]

b. CDC Guidelines

More recently, the Manufacturer Defendants collaborated through the PCF to coordinate opposition to the CDC's opioid prescribing guidelines before they were even issued. The CDC guidelines were "not good news" for the opioid industry and the PCF had formed a "broad work group" that included plans to "criticize the CDC process and expected outcomes" using "media efforts and recruiting patients and provider experts."[121] Indeed, by this time the Manufacturer Defendants knew that state-implemented prescribing guidelines hurt their opioid sales.[122] And since at least 2012 they and other PCF members, including the HDA, had worked together to convince the CDC that the true epidemic was untreated chronic pain, that it was the "#1 public health problem in the United States," was the true epidemic, and claiming that it was "unclear" why what they referred

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[117] Rosen Dep., Dkt. # 1970-10 at 210-215; Rosen Dep., Dkt. # 1970-10 at Exh. 25 (HDMA comment on draft stating "For now we shouldn't mention a certification requirement for physicians or anyone else, for that matter."); Exh. 174, EPI001038487 (email from Will Rowe to the PCF REMS Task Force that "reflects the concerns" expressed in meetings and is a "keep it simple" letter).

[118] Rosen Dep., Dkt. # 1970-10 at Exh. 26 at 6-7 (final version of letter sent to FDA); Rosen Dep., Dkt. # 1970-10 at 220 (confirming "That language is not in there"); Exh. 175, ENDO-OPIOID_MDL-02212590.

[119] Exh. 176, ENDO-OR-CID-00559762.

[120] Exh. 177, PPLP003985888; Exh. 4, PPLP004051807 at 08.

[121] Exh. 178, PPLP004266519 at PPLP004266520

[122] Exh. 179, PPLPC023000876706; Exh. 180, PPLPC023000876707 at 4 (showing decline in sales due to prescribing guidelines). Rosen Dep., Dkt. # 1970-10 at Exh. 27 at 13 (warning that prescribing guidelines and regulations "may have a negative impact" on sales); Rosen Dep., Dkt. # 1970-10 at 188-189 (agreeing that Ex. 27 warns of prescribing guidelines reducing sales); PPLPC011000093410 at 38, 270 (2016 internal document identifying guidelines as a risk to sales and stating that CDC guidelines will "likely to dampen opioid sales in the US" by $20-$47 million)

to as "opioid-related problems" were "considered to be of epidemic proportions."[123] Once the CDC released its guidelines, the Manufacturer Defendants used the PCF to undermine the guidelines because they were concerned that the guidelines were "likely to dampen opioid sales in the US" and "impact[] prescription habits globally."[124]

4. Physician Standards-Setting Organizations

The Manufacturer Defendants also incorporated their false and misleading messages about opioids into the standards that govern physician practice and hospital accreditation. While physician standards of care are set by the state medical boards, the content of those standards is heavily influenced by standards issued by a private organization, the Federation of State Medical Boards ("FSMB"). Similarly, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") is a private organization that issues standards for hospitals.[125]

a. Federation of State Medical Boards

Starting in 1998, several of the Manufacturer Defendants' front groups, as well as the Janssen-funded Robert Wood Johnson Foundation,[126] partnered to author the new standards of practice that would drive opioid prescribing. Robert Wood Johnson provided the funding, and the front groups,

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[123] Exh. 181, PPLPC019000632314; Exh. 182, PPLPC019000632316 at PPLPC019000632334 and PPLPC019000632337 (use of "opioid-related problems); Exh. 183, PPLPC018000617695; Exh. 184, PPLPC017000347668; Exh. 185, PPLP004282881; Exh. 186, PPLPC005000220230; and Exh. 187, PPLPC005000220232 at 3 (email asking PCF members to sign onto letter from CLAAD to HHS criticizing CDC guidelines as "appear[ing] to sacrifice the priority of meeting the medical needs of individuals with pain in favor of preventing opioid analgesic diversion and abuse"); Exh. 188, PPLP003892671 (email stating PFC discussed CDC guidelines); PPLPC019001182680 (email stating PCF "task" is to "review and respond to the new CDC guidelines" and proposing various potential actions to challenge or undermine them); Exh. 189, PPLPC017000683105 (email to PCF members looking to support legislation that may undermine CDC guidelines); Exh. 190, PPLPC017000687083 (email reflecting PCF VA task force goal of not having the VA follow the CDC guidelines); Exh. 191, PPLP004303706 (email that "CDC guidelines and related issues will be discussed" at upcoming PCF meeting); Exh. 192, PPLPC018001287703 (email warning PCF of potential amendment to VA bill that would require adoption of CDC guidelines that is also forwarded by Purdue to McKesson stating "Fyi as discussed").

[124] Exh. 193, PPLPC011000093411 at 52; *see also* Exh. 192, PPLPC018001287703 ("Pain Care Forum VA Task Force" to ensure that that Veterans Administration did not adopt the CDC guidelines); Exh. 194, PPLPC017000687083; Rosen Dep., Dkt. # 1970-10 at 100:18-101:7 (claiming to be unable to recall if he discussed opioid-related issues with Washington Legal Foundation); Exh. 195, PPLPC019001239393 (Rosen emails with Washington Legal Foundation arranging for lunch meeting to discuss CDC guidelines).

[125] https://www.successfactors.com/content/ssf-site/en/resources/knowledge-hub/educational-articles/joint-commission-compliance.html; *see also* Exh. 672, Miller Dep. at 214: 9-11 and 214:9-215:18.

[126] Exh. 673, PPLPC009000019931.

including AAPM, APS, and PPSG, "developed" the model guidelines "for state medical boards . . . for use in regulating the prescribing of controlled substances, such as opioids, in the management of chronic cancer and non-cancer pain."[127] Critically, the FSMB, as well as each of the front groups that drafted the model guidelines, were all members of the PCF.[128]

Not surprisingly, therefore, the model guidelines echoed the Defendants' common message, emphasizing the treatment of pain and trivializing addiction.[129] The guidelines also assured doctors that they "should not fear disciplinary action" for "prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose."[130] The guidelines did not identify any pharmaceutical company as an author.[131] The PPSG touted that it "played a central role" in revising the guidelines.[132]

The Manufacturer Defendants marketed these guidelines heavily, citing the FSMB 1998 Guidelines and 2004 Model Policy thousands of times.[133] Starting in 2007, Cephalon, Purdue, Endo, and Mallinckrodt provided funding to the FSMB to distribute the guidelines nationwide.[134]

b. Joint Commission for Hospital Accreditation

The Manufacturer Defendants also worked to incorporate their false and misleading messages about opioid prescribing into hospital standards for physicians through the JCAHO. As of 2016, nearly one third of physicians worked for hospitals or in practices partially owned by hospitals.[135] The JCAHO standards for accreditation are very influential on physicians in a hospital practice and

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[127] Federation of Medical Boards of the United States, Inc., *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (May 2, 1998) (hereinafter "FSMB, *Model Guidelines*").
[128] Exh. 1, PPLP004272094 at 96.
[129] *Id.*; ("inadequate pain control" may stem from "an inadequate understanding of addiction" that may result in "inadequate treatment of chronic pain patients."
[130] Federation of Medical Boards of the United States, Inc., *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*, Exh. 196, PKY181656516 at 18.
[131] E513_00028712
[132] Exh. 197, WIS_PPSG_008292 at 4; Exh. 198, WIS_PPSG_006938 (PPSG's David Joranson touted "the value of our work" to Purdue on the FSMB project with "much of it from behind the scenes.")
[133] Exh. 199, PKY181678252 (Purdue distributed 300,000 copies between 1999 and 2002).
[134] Exh. 674, FSMB0000017.
[135] https://www.ama-assn.org/practice-management/economics/first-time-physician-practice-owners-are-not-majority

"extremely important" to hospitals,[136] because JCAHO accreditation is necessary to receive Medicare or Medicaid funds.[137] Accreditation is determined in part by whether the hospital meets the JCAHO Standards.

In "1997, the [Janssen-funded] Robert Wood Johnson Foundation funded the Joint Commission to develop pain standards."[138] Dr. June Dahl, at the PPSG (one of the front groups), played a key role in developing the standards.[139] Although in 1998 JCAHO declined to include Dahl's proposed content that pain must be assessed in every new hospital patient,[140] one year later, Dr. Dahl approached a "differently composed committee" and these standards were adopted.[141]

Prior to the standards' 2001 publication, and in the several years thereafter, Purdue and Janssen contributed to the Joint Commission. Purdue gave $2.124 million to JCAHO between 2000 and 2003.[142]

II. "WE WANT NO INTERRUPTION IN THE SUPPLY CHAIN": MANUFACTURERS, DISTRIBUTORS, AND PHARMACIES JOIN FORCES

While the Manufacturer Defendants laid the foundation for the conspiracy, in part through the RICO Marketing Enterprise, they soon realized that they could not capitalize on their marketing efforts unless they could fill the skyrocketing demand for opioids they had created. There were two obstacles. First, the manufacturers relied on distributors and pharmacies to get their product to market. Second, the sale and distribution of controlled substances, such as opioids, are heavily regulated under the Controlled Substances Act, which requires all registrants within the closed system to play a part in guarding against diversion, to include identifying "suspicious orders," reporting them to the DEA, and halting their shipment. To overcome these hurdles and maximize their profits, the

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136 Exh. 672, Miller Dep. at 214: 9-11.
137 Exh. 672, Miller Dep. 214:9-215:18.
138 Joint Commission on Accreditation of Healthcare Organizations, *Pain Standards for 2001* (2001); https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf.
139 Exh. 200, PKY182577992 at 182578131; Exh. 62, PKY180470186; Exh. 201, PKY180772092.
140 Exh. 672, Miller Dep. at 233:1-236:14.
141 Exh. 672, Miller Dep. at 227:13-237:8.
142 Exh. 58, SFC00000001 (Purdue); Exh. 60, JAN-MS-00000001 (Janssen).

Manufacturer Defendants began to partner with distributors and pharmacies to ensure that their opioids would be sold down the line with no interruption in the supply chain. From these interactions the RICO Supply Chain Enterprise was also born.

A. The Beginnings of the Supply Chain Enterprise

Around 1996, when Purdue's OxyContin was first launched, Purdue recognized that "over 80% of the current drug market [was] controlled by four players: McKesson, Bergen, Cardinal, and AmeriSource."[143] To ensure that every wholesaler stocked OxyContin and that its products could be marketed more efficiently, Purdue began to build relationships with these "wholesaler trading partners."[144] The goal of these connections was always to increase industry profits from sales.[145]

Around this same time, the Distributor Defendants, largley through the HDA, began to get together with other industry stakeholders, such as NACDS,[146] to discuss "concerns regarding statutory requirements to report to DEA what are commonly referred to as suspicious orders."[147]

B. DEA's "Distributor Initiative": Reminding Registrants of Their CSA Duties

In 2005, in response to the growing opioid crisis, DEA Deputy Assistant Administrator Joseph Rannazzisi launched "the Distributor Initiative" to warn all registrants (manufacturers, wholesalers, and pharmacies) selling or distributing prescription opioids in the closed, controlled substances system that it was unacceptable to ignore their gatekeeper obligations to guard against diversion.[148] Rannazzisi and the DEA led briefings with numerous distributors reminding them of their duties under the

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[143] Exh. 202, PKY181715440 at 442.

[144] *Id.* at 442 ("participation in a variety of wholesaler programs with the launch of OYXCONTIN insured that every wholesaler distribution center would stock OXYCONTIN"); *Id.* (Purdue identified a need to "help our wholesaler bring their products to market more efficiently" because "[p]roviding efficiencies to our wholesaler would also mean gaining efficiencies in our business"); *Id.* at 443 ("Contacts there [with distributors] will facilitate us moving effortlessly through the organization.").

[145] *Id.* ("With wholesaler friendly policies from us, we can expect programs that will be friendly and profitable to our Company").

[146] *See*, *id.* at Appendix E Membership List; Exh. 203, CAH_MDL2804_02201987 at 02202063 (Appendix E Membership List).

[147] Exh. 203, CAH_MDL2804_02201987 at 02201995; *see also* https://web.archive.org/web/20020603074959/http://www.deadiversion.usdoj.gov/pubs/program/sotf/index.html.

[148] Rafalski Rep., Dkt. # 2000-22 at 16; Exh. 204, US-DEA-00000352; Exh, 205, US-DEA-00000369; Exh. 206, US-DEA-00000371; Exh. 207, US-DEA-00000147; Exh. 208, US-DEA-00000144.

Controlled Substances Act and its implementing regulations.[149] DEA focused on registrants' obligation to design and operate a system that identifies suspicious orders.[150] DEA instructed registrants that, prior to shipping any order that was determined suspicious, the distributor should conduct due diligence to ensure the controlled substances were not likely to be diverted, and document their due diligence actions.[151] In 2006 and 2007, the DEA cautioned the entire industry as to their suspicious order monitoring duties in a series of letters.[152]

In April 2007, the DEA suspended AmerisourceBergen's registration to distribute controlled substances from its Lakeland, Florida distribution center because of its failure to maintain effective diversion controls.[153] AmerisourceBergen entered into a settlement agreement whereby it agreed to overhaul its suspicious order monitoring system to stop shipments of suspicious orders and to improve its due diligence process.[154] This suspension was quickly followed by suspensions of McKesson's and Cardinal Health's registrations in 2008.[155]

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[149] *Id.* Kelly Dep., Dkt. # 1963-14 at 46 (in 2005, DEA began meetings with wholesale distributors); Thomas Prevoznik Dep. (04/18/19), Dkt. # at 470:16-470:24; Exh. 209, CAH_MDL_PRIORPROD_DEA_12_00011059; HDS_MDL_00002032 at 2040; Exh. 210, ABDCMDL00315887 and Exh. 211, US-DEA-00003881 (August 10, 2005 AmerisourceBergen DEA Presentation); Exh. 212, CAH_MDL_PRIORPROD_DEA07_01178736 (August 22, 2005 DEA Presentation to Cardinal Health); Exh. 213, US-DEA-00000168 (September 9, 2005 meeting materials and DEA Presentation to Anda); Exh. 214, HDS_MDL_00449519 (January 4, 2006 DEA Presentation to H.D. Smith); Exh. 215, MCKMDL00708429 (September 1, 2005 McKesson DEA Presentation).

[150] *See* 21 U.S.C. § 843(e); 21 C.F.R. §§ 1301.71(a); 21 C.F.R. § 1301.74(b).

[151] *Id.*; *see also* Exh. 204, US-DEA-00000352 at 00000360; *See* Rafalski Rep., Dkt. # 2000-22 at 15-21; *see e.g.* Exh. 216, CAH_MDL_PRIORPROD_DEA07_00837645; Exh. 217, CAH_MDL_PRIORPROD_DEA07_00092296.

[152] Exh. 204, US-DEA-00000352, 00000360; *See* Rafalski Rep., Dkt. # 2000-22 at 17-21; *see e.g.* Exh. 216, CAH_MDL_PRIORPROD_DEA07_00837645; Exh. 217, CAH_MDL_PRIORPROD_DEA07_00092296.

[153] *See* Exh. 218, ABDCMDL00269383-86 (April 19, 2007 Order to Show Cause and Immediate Suspension of Registration); *see also* Kelly Dep., Dkt. # 1963-14 at 47-48.

[154] Christopher Zimmerman Dep. (08/03/18), Dkt. # 1972-16 at 139:16-140:13; *see also* Exh. 219, ABDCMDL00279854-65 (2007 Settlement and Release Agreement).

[155] McKesson: https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders ("In 2008, McKesson agreed to a $13.25 million civil penalty and administrative agreement for similar violations"); https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf (documenting that "DEA alleged that McKesson failed to maintain effective controls . . . against diversion of controlled substances" at multiple distribution centers).
Cardinal Health: https://ir.cardinalhealth.com/news/press-release-details/2008/Cardinal-Health-Resolves-Controlled-Substance-License-Suspensions/default.aspx ("The administrative and civil settlement agreements also resolve all DEA claims related to the company's controls against the diversion of controlled substances").

These suspensions, which were a direct threat to the entire opioid industry's continued business, lit a fuse within the industry.[156] The very real threat of DEA enforcement prompted a flurry of communication and coordination among all members of the supply chain, including members of the PCF, HDA, and NACDS, to find a solution to protect their businesses.[157] As early as November 2007, HDA and NACDS jointly discussed a response to DEA's initiative.[158] One of HDA's goals, which it shared with NACDS, was to "develop a comprehensive DEA strategy" to avoid enforcement actions against Distributors.[159] As part of this strategy, the Defendants, including through the HDA and NACDS, discussed the CSA's legal requirements, including the fact that distributors were required not to ship suspicious orders, and what their response should be.[160] The HDA voted as to whether, if "an order is potentially suspicious, *should* the distributor be able to ship part of the order,"

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[156] *See e.g.* Exh. 220, PKY180149804; Exh. 221, PPLPC024000142048; Exh. 222, CAH_MDL_PRIORPROD_DEA12_00000488; Exh. 223, CAH_MDL_PRIORPROD_DEA07_00828632 (April 25, 2007 email regarding Cardinal's discussion with ABC about ABC suspension); Exh. 224, PPLPC004000110840 (April 25, 2007 Email from S. Seid at Purdue stating he will "try to talk to ABC today."; Exh. 225, PPLPC004000110984 (April 25, 2007 Email from Stephen Seid stressing that what is important is to "insure access" and that he had "been in contact with AmerisourceBergen offering our assistance in providing expedited support and service"; Exh. 226, PPLPC019000138521 (April 25, 2007 email from Purdue's Supply Chain Security Director to Watson employee looking for information on ABC suspension); Exh. 227, PPLPC019000138530 (April 25, 2007 email from Purdue's Supply Chain Security Director to Cardinal employee looking for information on ABC suspension); Exh. 228, PPLPC019000138537 (April 25, 2007 email from Purdue's Supply Chain Security Director to UPS employee discussing the ABC suspension; Exh. 229, PPLPC020000126172 (April 25, 2007 email from Purdue's Supply Chain Security Director to McKesson employee asking for information about the ABC suspension); Exh. 230, MNK-T1_0000492297 (April 26, 2007 email between Mallinckrodt employees stating one of them had spoken with ABC and had been told that "the issue has been resolved and they [ABC] should be able to distribute controlled substances as of today."; Exh. 231, MCKMDL00543043 (April 27, 2007 internal McKesson email relating that McKesson's Gary Hilliard had spoken with his ABC counterpart and learned that "ABC did not expect this at all, they like us had been going back and forth with DEA over the past 18-20 months also but thought they had satisfied DEA. The ABC rep indicated that he thought Cardinal was experiencing some challenges also."; Exh. 232, CAH_MDL_PRIORPROD_DEA07_00842131 (December 2007 email from Jack Crowley of Purdue to Elaine Troutman referring to the Lakeland, Florida distribution suspension and stating "I'm sorry that DEA is being so aggressive with this Suspicious Orders stuff. . . . I wish there was something I could do to help in this situation – we are all in the same boat.").

[157] Exh. 233, CAH_MDL_PRIORPROD_DEA07_00877471 (expressing concern about the "intensity and impact of the Drug Enforcement Administration's recent actions.").

[158] HDA_MDL_000218911; Exh. 234, HDA_MDL_000067937.

[159] Exh. 233, CAH_MDL_PRIORPROD_DEA07_00877471; Kelly Dep., Dkt. # 1963-14 at 62.

[160] Kelly Dep., Dkt # 1963-14 at 160:7-170:12; Exh. 235, CAH_MDL_PRIORPROD_DEA07_00877084 (HDA and NACDS attended September 2007 DEA Pharmaceutical conference in which DEA reminded registrants that they are required to report suspicious orders and halt shipments of suspicious orders); Exh. 233, CAH_MDL_PRIORPROD_DEA07_00877471 ("Given the need to keep up with the DEA's fast pace," the HDA asked that "those attending be prepared to fully assess the impacts and [be]authorized to speak on, and agree to, policy and strategy decisions on behalf of their companies."); Exh. 236, HDA_MDL_000213427 (McKesson to meet with HDA to discuss "plan to deal with . . . DEA").

"consistent with the current practice for many distributors."[161] HDA members also asked, "Should we support DEA's [law enforcement] efforts?"[162] Defendants' subsequent actions made clear the answer to that question.

C. Defendants Bind Together To Protect The Supply Chain

Purdue voiced the common mission: "We want no interruption in the supply chain."[163] The goal was to keep sales flowing, which was evident from Perdue's question when it learned that 4.2 million oxycodone pills were dispensed in Florida, alone, in 2008: "What's wrong with that?"[164] And when one distributor's registration was at risk because of a failure to maintain effective diversion controls, Purdue was unconcerned about the possible legal violation, explaining that its "primary focus is to help [the distributor] protect its registration and its business in general and especially in distributing our products. We are very appreciative of their work in assuring that our medicine reaches our patients in an appropriate manner and in a timely fashion."[165]

Purdue was in good company. Indeed, a Teva employee was instructed to release two held orders because "'Our business reason for these two orders is we need to supply our customer with product because they won't be able to fulfill their customers[']' demand without it.'"[166] In response, the Teva employee found the singular focus on protecting the supply chain "a bit shocking": he stated that, "we knew this was the culture here but to see someone put it in an email is a bit shocking. . . . he is basically saying he does not care where the product goes just that . . . we continue to ship."[167] Mallinckrodt was similarly focused on shipping orders without delay. One of its employees received an email from a distributor, who had received an overnight shipment of 1200 bottles of oxycodone from Mallinckrodt, and wrote: "Keep'em comin'! Flyin' out of here. It's like people are addicted to

[161] *See* Kelly Dep., Dkt. # 1963-14 at 208.
[162] *See* Kelly Dep., Dkt. # 1963-14 at 77-79.
[163] Exh. 237, PPLPC053000021255 at PPLPC053000021256-PPLPC053000021259.
[164] Exh. 238, PPLPC018000440751.
[165] Exh. 239, PPLP004460406.
[166] Exh. 240, TEVA_MDL_A_01454702.
[167] Exh. 240, TEVA_MDL_A_01454702.

these things or something. Oh, wait, people are . . ."[168] The Mallinckrodt employee responded: "Just like Doritos keep eating. We'll make more."[169]

1. Purdue Leads the Charge, Partnering With Distributors for "Mutual Support"

Particularly in light of the Distributor Initiative and its threat to the supply chain, the manufacturers began to partner with the distributors; otherwise the manufacturers had no control over the sales of opioids once the drugs left the manufacturers' hands. As Purdue explained, the manufacturers could not solve the DEA problem on their own:[170] "**The responsibility for making the decision to ship rests with the supplier. . . . That is why we must collaborate**."[171] For the Defendants, it was important to "pledge to remain in close contact with each other whenever there may be a questionable order" in order to "**protect ourselves and our registrations regarding suspicious order discovery and reporting**."[172]

Purdue further explained: "We really do have to partner with our own customers to help them in their business with pharmacies catering to 'pain clinics.' Otherwise, [distributors] will cut [the pain clinics] off based on some kind of threshold. We need to convince [distributors that] they should talk to us when our product is involved and make it a joint decision, etc. just as we need to consult with them from our end."[173] Collaboration was about filling orders, not stopping them: "We are not about to hold [an] order while we take our time deliberating. We want no interruption in the supply chain."[174]

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[168] Email Chain Between Victor Borelli and Steve Cochran Re Oxy 30 (Jan. 27, 2009) (emphasis added), (Exh. 241, MNK-T1_0000559532.). That same Mallinckrodt employee himself once described his job using the phrase "ship, ship, ship," and emailed a distributor client asking them to check their inventories and "[i]f you are low, order more. If you are okay, order a little more. Capesce?"; and joked that the distributor should "destroy this e mail… Is that really possible? Oh Well…." *See* Email from Victor Borelli to Steve Cochrane, Re. things (May 20, 2008), Exh. 242, MNK-T1_0000506535.
[169] *Id.*
[170] Exh. 237, PPLPC053000021255 at 53000021256-59.
[171] *Id.* at 5300021258 (emphasis added).
[172] *Id.* at 53000021257 (emphasis added).
[173] Exh. 243, PPLPC018000200323 at 18000200324.
[174] Exh. 237, PPLPC053000021255 at 53000021259.

Recognizing the importance of these relationships,[175] Purdue led the charge, focusing on partnerships with its "distributor counterparts."[176] To that end, in 2008, Purdue "arrange[d] a meeting with the Big 3 . . . to talk about DEA's latest plans "to squeeze the wholesalers and distributors on 'pain clinics.'"[177]

In early 2008, AmerisourceBergen met with Purdue to focus on "Business & Diversion" and "communication and cooperation" between Purdue and ABDC[178] in relation to suspicious order monitoring.[179] The meeting was so valuable from AmerisourceBergen's perspective that it recommended holding further meetings with Purdue, but expanding them to include Cardinal and McKesson.[180]

Purdue and Cardinal Health met to "collaborate with Cardinal on issues about our product(s)," because Purdue felt that it was very important "to collaborate and support [Cardinal] on any accounts we feel might require further assessment, etc."[181] In other words, Purdue was concerned about the distributor's ability, and perhaps obligation in some circumstances, to stop orders, and wanted to work with the distributor to prevent any such hiccups in the supply chain, which would lead to lost profits for both. The purpose of these meetings between Purdue and the Distributors focused on helping

[175] Exh. 244, PPLPC004000146532 (Jack Crowley states in an email chain about suspicious orders, "I understand how important these [distributor] relationships are, etc. and the potential impact on distribution of our product.").
[176] *Id.*
[177] Exh. 243, PPLPC018000200323. Purdue identified the appropriate people to meet with at each of the large distributors during this time, including: "Greg Halvacs (Cardinal); George Euson (H.D. Smith); Chris Z (Amerisource)j [sic] Bob Pocica (McKesson); and Chris Berry (Henry Schein)." *Id.* These individuals were identified as "men I consider to be personal friends of mine," evidencing the personal relationships between Purdue and these Distributors.
[178] Exh. 245, PPLP004385367.
[179] Exh. 246, PPLPC004000182848 at 4000182848-49 (SOM is the abbreviation for Suspicious Order Monitoring, and OMS is the abbreviation for Order Monitoring System).
[180] Exh. 247, ABDCMDL00364944 at 364944.
[181] Exh. 248, CAH_MDL2804_00879572 at 00879573.

the industry protect itself from "over-zealous regulators."[182] Purdue emphasized that the "purpose certainly is . . . not to 'second guess' etc." the distributors.[183]

Purdue met with McKesson in 2009 about suspicious order monitoring and their systems for doing so.[184] Purdue proposed a "collaborative effort" regarding Suspicious Order Monitoring.[185] McKesson stated, "that [it] was in 100% agreement with Purdue and . . . recognized that this collaborative effort was the right thing to do."[186] As McKesson stated, "we ultimately protect ourselves."[187] Purdue noted to McKesson that "Joe Rannazzisi [of the DEA] is publicly stating that 'Manufacturers are now sending letters to their wholesale distributor consumers warning them of their due diligence obligations. . .,' our Purdue Team does not and will not operate in that manner."[188] McKesson and Purdue met again in 2010 for the purpose of "further cooperation between Purdue and McKesson to develop coordinated protocols for communication in the identification of patterns of interest to all of us."[189]

On August 18, 2009, Purdue's Jack Crowley communicated with both H.D. Smith and Cardinal Health, stating "[w]e should gang up on DEA in Portland, OR," referring to an upcoming DEA diversion conference for the pharmaceutical industry in Portland.[190] Purdue maintained regular

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[182] *Id.* ("This isn't a situation where we could be questioning you etc. - nay, nay - this is a support function for industry to do the right thing, support itself and each other, protect itself from over-zealous regulators - and ensure that patients receive their appropriate medication in a timely fashion").
[183] *Id.* at 00879572.
[184] Exh. 249, PPLP004474439.
[185] Exh. 249, PPLP004474439-40; Exh. 250, MCKMDL00536290.
[186] *Id.* at 4474440.
[187] *Id.*
[188] Exh. 250, MCKMDL00536290.
[189] Exh. 251, PPLPC053000039688. Notably, this statement was made by Purdue in an email written to H.D. Smith while describing the purpose of the McKesson meeting suggesting that the patterns were of concern to the entire industry, not just McKesson and Purdue.
[190] Exh. 252, HDS_MDL_00086622; Exh. 253, CAH_MDL2804_00851292.

contact with AmerisourceBergen,[191] Cardinal Health,[192] and McKesson[193] about prescribers of concern, potentially suspicious accounts, and whether or not to report or stop suspicious orders (or cut off suspicious customers). Purdue and McKesson agreed that the purpose of their communication was not to improve compliance, but to "maximize [their] shared objectives."[194] Similar discussions occurred with all of the Big Three after it came to light in 2011 that H.D. Smith was experiencing a DEA problem because of its distribution in Florida.[195]

The suspension of Cardinal Health's registration in 2012 reinvigorated these partnerships, including immediate coordination calls between Purdue, Cardinal Health, and McKesson, followed by information sharing with AmerisourceBergen[196] and McKesson.[197] They reaffirmed the need for "mutual support": "We look at our work together as 'mutual support' as we are all in this together - manufacturers and wholesalers/distributors - as well as retail customers, of course."[198] Moreover,

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[191] Exh. 254, PPLPC021000249399. On August 26, 2009, Purdue identified "No Call" physicians to ABDC and explained that if ABDC did not want this information for its files then both companies could delete the email. *Id.* *See also*, Exh. 255, PPLPC019000346516 at 19000346516-19; Exh. 256, PPLPC034000451465; Exh. 257, PPLP004469304 (a heavily redacted email with subject line "mutual support" revealing coordination between Purdue and ABDC through their respective employees, Jack Crowley an Ed Hazewski).

[192] Exh. 258, PPLP004473046.

[193] Exh. 259, PPLP004473318 at 4473319. *See also* Exh. 260, PPLP004437208 at 4437209-15; Exh. 261, PPLP004469394; Exh. 262, PPLPC023000285327; Exh. 263, PPLP004473227; Exh. 264, PPLPC018000502666 at 18000502667-70; Exh. 265, PPLPC020000496773.

[194] On June 24, 2010, Purdue instructed McKesson not to reveal Purdue as a source of information to third parties unless it is the DEA. Exh. 266, MCKMDL00634412. Purdue specified that this was a practice that "might be mutually beneficial to repeat in light of prior emails." *Id.* Purdue continued, requesting that McKesson "please let us know when you report concerns about specific pharmacies to any [government] entities. We will observe the same protocol with any information you share with us . . . with respect to specific outlets you service. That way we'll each know what the other is doing and can coordinate our efforts to maximize our shared objectives." *Id.*

[195] In March of 2011, Purdue became aware that H.D. Smith was having "significant issues" with the DEA and in danger of being shut down. Exh. 267, PPLPC004000274124. "H.D. Smith is selling 75 percent less oxycodone this year than last in Florida" and "will only begin distribution of oxycodone again if they are 100% comfortable with the account – 100%!" *Id.* at 4000274126. Purdue determined "that [they] could help H.D. Smith and George Euson if [they] wanted to get involved" and decided that the H.D. Smith action impacts us . . . so I think it's a good thing for us to get involved." *Id.* at 4000274124. Purdue then began to "touch base with other 3 [distributors] to see if they are making any significant changes in S Florida." *Id.*

[196] Exh. 268, PPLP004472303 (reflecting Purdue and ABDC sharing information about pharmacy customers).

[197] Exh. 269, PPLPC004000310913; *see also* Exh. 270, ABDCMDL00301700; Exh. 271, PPLP004473294 at 4473295-96; Exh. 272, PPLPC020000558069; Exh. 273, PPLPC022000513320 at 22000513320-21; Exh. 274, MCKMDL00575490 at 575491-92.

[198] Exh. 273, PPLPC022000513320 at 22000513321.

despite Cardinal Health's registration suspension for violating the law, Purdue was eager to continue "collaboration of efforts and mutual support."[199]

In 2014, McKesson noted that it had met with its "manufacturing partners," including "Mallinckrodt, Purdue, and Actavis," to "share with them our controlled substance monitoring information and identify opportunities for collaboration," and had further met with CVS to review SOM.[200]

The purpose of the meetings between the Manufacturer Defendants and the Distributor Defendants was always the same: "collaboration" and an effort to "come together" so that manufacturers could gain influence and control over what happened downstream to keep the supply chain goin and maximize profits (*i.e.*, mutual support).[201]

2. The Distributors Coordinate With Each Other

While Purdue initiated alliances with the Distributor Defendants, the Distributor Defendants were also partnering with each other concerning the DEA and suspicious order monitoring requirements. For example, in November 11, 2010, H.D. Smith approached Cardinal Health about a "working group meeting to include representatives from the major wholesalers and possibly manufacturers," to discuss "how the major wholesalers could possibly collectively address due diligence efforts."[202] The Distributor Defendants met face-to-face at the HDA on March 1, 2011, to discuss DEA regulations and order monitoring.[203]

In 2012, H.D. Smith scheduled a "meeting with the Big 3 to discuss DEA issues."[204] They discussed customer accounts, some of which had been cut off by one distributor and picked up by

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[199] Exh. 275, PPLP004473076; Exh. 276, PPLPC022000560403; Exh. 277, PPLPC051000161341; Exh. 278, CAH_MDL2804_01724286 (email between Purdue and Cardinal) ("I look forward to collaborating with you and supporting your team on matters of mutual interest.").
[200] Exh. 279, MCKMDL00707097.
[201] Exh. 280, PPLP004473400 at 4473401, 4473404, 4473405.
[202] Exh. 281, HDS_MDL_00095924.
[203] Exh. 282, HDS_MDL_00218631; Exh. 283, HDS_MDL_00218806; Exh. 284, HDS_MDL_00218808.
[204] Exh. 285, HDS_MDL_00237637; Exh. 286, HDS_MDL_00100037.

other distributors.[205] The group agreed that "this type of meeting and exchange was valuable and should continue quarterly."[206]

Representatives from the Big Four (*i.e.*, the Big Three plus H.D. Smith) orchestrated a number of meetings to share information and discuss ongoing DEA issues and suspicious order monitoring between 2012 and 2013.[207] The distributors confirmed the usefulness of information sharing and "resolved to conduct something similar to it in the next six months or so."[208] After the meeting, information sharing continued:

> Interesting gossip came from [Cardinal Health's] Reardon/Quintero, who related that **Cardinal is not reporting suspicious orders to DEA on the advice of outside counsel** (appears to be Linden Barber) . . . "**we don't get any credit for doing it, it appears there is no upside** . . ."[209]

Big Four meetings continued until as recently as 2017, facilitated by the HDA.[210] Focusing on "specific agenda topics that [the group] would like to discuss related to DEA, diversion control, or other regulatory topics."[211]

In late 2011, the DEA expanded enforcement efforts to manufacturers as well. As Purdue explained to other manufacturers, the DEA was threatening to reduce manufacturers' production quotas (*i.e.*, the amount of opioids that manufacturers were permitted to sell) by the same percentage of diversion that DEA could prove.[212] Around the same time, Purdue noted that the DEA did not

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[205] Exh. 286, HDS_MDL_00100037. In the notes from this meeting, there is a statement about an account that H.D. Smith had "exited" due to Oxycodone concerns, but that AmerisourceBergen and Cardinal had picked up at different times. The Big Four stated they should continue sharing this kind of information. *Id.*

[206] *Id.* at 38.

[207] Exh. 287, HDS_MDL_00239748 (discussing getting all four distributors together for a meeting with the New York City Police. The Big Four distributors met in person to discuss diversion.); Exh. 288, CAH_MDL2804_01310643; Exh. 289, HDS_MDL_00108090; Exh. 290, ABDCMDL00378483. Notably, the HDA was aware that its Big Four members were having meetings like this because ABDC's Steve Mays "talked to HDMA about getting us a meeting room at the hotel and they will take care of that." *Id.* *See also*, Exhibit 291, MCKMDL00545341 at 00545342.

[208] Exhibit 291, MCKMDL00545341 at 00545342.

[209] *Id.* at 00545341, 00545342 (emphasis added).

[210] Exh. 292, HDA_MDL_000212563; Exh. 293, HDS_MDL_00493053; Exh. 290, ABDCMDL00378483.

[211] Exh. 290, ABDCMDL00378483; *see also* Exh. 292, HDA_MDL_000212563.

[212] Exh. 294, PPLPC020000517972; Exh. 295, TEVA_MDL_A_01453996.

"appreciate" "just how jittery industry is."[213] Purdue realized that the entire industry had to come together, including "MFR-Dist-Retail."[214]

3. Industry Comes Together to Evade Compliance: A Race to the Bottom

As the conspiracy evolved, the Defendants partnered both vertically and horizontally, individually and in groups, to find ways to circumvent the controlled substance regulations. Defendants' various business relationships and organizations were critical to helping each other conceal from the DEA their failures to maintain effective diversion controls.

Consistent with their goal to not interrupt the supply chain, the Manufacturer Defendants flagged, but failed to take further action on, suspicious orders from the Distributor and Pharmacy Defendants. For example, in a review of its suspicious order monitoring (SOM) system, Mallinckrodt noted that half of the flagged orders on its "peculiar order" reports were from McKesson, AmerisourceBergen, and Cardinal, and a "significant amount" were from "large retail chains CVS, Walgreens, Walmart," but it internally decided not to elevate any orders from "peculiar" to "suspicious."[215]

Plainly trustful of its relationship with Purdue, McKesson revealed that "McKesson does not use the word 'suspicious', but rather questionable or (sometimes) noteworthy."[216] McKesson had earlier instructed its employees not to use the term "suspicious orders" since that could trigger legal obligations:

> With the recent fines and ongoing attention being paid to this issue, it is quite possible that wholesalers will be under scrutiny for quite some time. All communications regarding controlled substances will therefore be subject to subpoena and discovery. . . . Refrain from using the word 'suspicious' in communications. Once we deem an order and/or customer suspicious, McKesson is required to act. This means

[213] Exh. 296, PPLPC026000087658.
[214] Exh. 280, PPLP004473400 at 4473401, 4473404, 4473405.
[215] Exh. 297, MNK-T1_0000422314. *See also* Suspicious Order Monitoring Program No. C/S Comp 3.0, (Oct. 29, 2010) Exh. 298, MNK-T1_0000264260 (establishing threshold for identifying "peculiar" orders and setting forth procedure for reviewing and classifying peculiar orders as "suspicious" and elevating these orders to DEA report status.)
[216] Exh. 259, PPLP004473318 at 4473319.

> all controlled substances sales to that customer must cease and the DEA must be notified."[217]

In 2013, Endo held a meeting with CVS and Cardinal to discuss NACDS, SOM, and opioids.[218] Similarly, in July 2013, Purdue met with distributors, including Amerisource, McKesson, Cardinal, and H.D. Smith, and pharmacies, including Walgreens, Rite Aid, and Walmart, to discuss SOM issues, like DEA actions, and thresholds.[219] ("Threshold" is a term used in SOM systems to describe a ceiling or limit, beyond which orders should be flagged as suspicious for due diligence review and reported.[220]) Purdue discussed with Walgreens that its pharmacists, who were making five to six calls a week to confirm prescriptions were valid, were "overzealous" and "calling too much."[221] Purdue described these pharmacists as being "ultra-conservative," and that their approach was being "[d]riven by DEA actions, DOJ finds, and ongoing investigations."[222]

As detailed below, the Manufacturer Defendants shared information with each other and the Distributor Defendants, such as SOM programs and customer information, in a "race to the bottom." Instead of coordinating to improve their compliance with diversion, they were sharing techniques and information about how to do as little as possible so that the supply chain was not interrupted. Meanwhile, they were simultaneously putting up a front of compliance by "revising" their SOMS so that they would not get caught up in the DEA's enforcement efforts.

Mallinckrodt – Mallinckrodt's direct interactions with the Distributor Defendants increased in 2008 during its purported remodel of its suspicious order monitoring program, and by 2011,

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[217] Exh. 299, MCKMDL00634271.

[218] Exh. 300, ENDO-OPIOID_MDL-02896825.

[219] Exh. 301, PPLPC004000363085 (noting that NACDS was working with the Pain Care Forum on industry wide issues related to SOM). *See also* Exh. 302, PPLP004436880 (listing earlier meetings).

[220] *See* Rafalski Rep., Dkt. # 2000-22, at 15-16, (quoting the DEA Diversion Manual (DEA Diversion Investigators Manual (1996) Exh. 303, CAH_MDL2804_02203353):

> The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.

[221] Exh. 301, PPLPC004000363085.

[222] Exh. 301, PPLPC004000363085.

Mallinckrodt was holding face-to-face meetings with the Distributor Defendants to obtain customer information, which enabled them to identify suspicious orders.[223] Mallinckrodt also directly interacted with the other Manufacturer Defendants by assertively working with them on the creation or modification of their suspicious order monitoring systems.[224] Mallinckrodt formed the ADIWG[225] as another forum to address SOM.[226]

Teva/Cephalon – Aside from its work founding the PCF with Purdue, and later memberships in the HDA, NJPIG, and ADIWG, Teva and Cephalon collaborated with the Defendants purportedly to design and implement a suspicious order monitoring system.[227] Teva consulted with Purdue, Mallinckrodt, and Actavis,[228] and distributed questionnaires to the distributors about their suspicious order monitoring programs so that Teva could "develop a benchmarking survey" about the same.[229] Teva maintained a special relationship with the Distributor Defendants, particularly the Big Three.[230]

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[223] *See*, *e.g.*, Exh. 304, MNK-T1_0000471985; Exh. 305, MNK-T1_0000281750; Exh. 306, MNK-T1_0000311707. The interaction between Mallinckrodt and the Distributor Defendants also included mailing letters to those entities if/when one of their customer's orders raised concerns. Notably, these letters tied the discovery of ordering patterns of concern using chargeback data. *See* Exh. 307, MNK-T1_0000491718; Exh. 308, MNK-T1_0000491713; Exh. 309, MNK-T1_0000491723. The interactions between Mallinckrodt and the Distributors also included the exchange of chargeback data and the execution of non-disclosure and restricted use agreements. Exh. 310, MNK-T1_0000574277; Exh. 311, MNK-T1_0000574362; Exh. 312, MNK-T1_0000574570.

[224] Exh. 313, TEVA_MDL_A_01463623.

[225] Mallinckrodt formed the ADIWG with the members including Cardinal Health, AmerisourceBergen, McKesson, H.D. Smith, Actavis, Qualitest (Par/Endo), and Quarles & Brady. Exh. 314, MNK-T1_0008191086; 087; 089; 090; 093.

[226] In 2017 Purdue invited Mallinckrodt to "brainstorm" ideas related to this litigation and public policy issues related to the opioid epidemic. Exh. 315, PPLPC018001476486. Mallinckrodt was also working, at the time, with Endo and McKesson on public relations issues aimed at deflecting negative attention on their role in the opioid epidemic. Exh. 316, ENDO-OPIOID_MDL-06229886 – 888; Exh. 317, MCKMDL00667620 – 628.

[227] Exh. 318, TEVA_MDL_A_06925565. In 2012, Teva hired Buzzeo PDMA to audit its monitoring system, revealing that Teva never reported a single suspicious order and its customer due diligence process was limited to checking registration and credit worthiness. Exh. 319, Teva_MDL_A_01463855. The audit also revealed that the order monitoring system was "not sufficiently sensitive to customer ordering practices to result in any meaningful analysis of customer order practices." *Id.*; *see also* Exh. 319, Teva_MDL_A_01463855.

[228] Exh. 295, Teva_MDL_A_01453996; Exh. 313, TEVA_MDL_A_01463623; Exh. 320, TEVA_MDL_A_02331289; Exh. 321, TEVA_MDL_A_01056183.

[229] Exh. 322, TEVA_MDL_A_01457292. Teva also executed non-disclosure agreements with distributors for chargeback and suspicious order monitoring information, coordinated with Mallinckrodt and Actavis regarding suspicious order monitoring programs, and communicated with the Distributor Defendants regarding potentially suspicious customers. Exh. 323, CAH_MDL2804_01659931; Exh. 320, TEVA_MDL_A_02331289; Exh. 321, TEVA_MDL_A_01056183.

[230] Notably, when Teva wanted to develop its suspicious order monitoring system it repeatedly hired AmerisourceBergen employees for the task, who had designed a system that the DEA had found insufficient on multiple occasions. Kevin Kreutzer Dep. (11/27/18), Dkt. # 1963-21 at 19:3-21:23, 104:19-105:19, 218:2-223:3 (also acknowledging meetings between Teva and Mallinckrodt, as well as meetings with AmerisourceBergen, Cardinal Health, McKesson, and either

When asked: "Are we evaluating orders from the Big 4 different than the rest," the answer was - "Yes, I am not scrutinizing the Big 4 as closely as the secondary distributors and retail pharmacy chains. We all know the Big 4 especially, ABC, Cardinal and McKesson have all had previous fines against them for not having a sufficient SOM program."[231] In essence, Teva admitted that it was giving preferential treatment to the Big Four distributors, even though it knew they were not complying with the law and that their orders, therefore, were the ones that deserved the most scrutiny.

Allergan – Allergan's direct interactions with other Defendants increased in 2012 when Allergan requested advice from Purdue about a new suspicious order monitoring system and began attending NJPIG meetings to learn about other Defendants' order monitoring systems.[232] Allergan also began re-negotiating contracts with the Distributor Defendants to include customer sales, *i.e.* chargeback data, as part of Allergan's indirect SOM process that included "phone calls and visits to distributor customers."[233] The discussions "[included] an overview of [Allergan's] indirect SOM process and the need for some level of secondary sales or distribution information from our customers [*i.e.* the Distributor Defendants] about where [Allergan] product is going and may touch on termination of orders that cannot be justified as legitimate."[234]

Endo – Endo cooperated with the Distributor Defendants to analyze their chargeback data as part of its suspicious order monitoring program.[235] Endo also mailed questionnaires to the Distributors regarding their suspicious order monitoring processes and executed non-disclosure/restricted use agreements in order to facilitate sharing of suspicious order monitoring data.[236] After Endo purchased Par Pharmaceuticals in 2015, Endo further communicated with the

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Morris Dickson or HD Smith, regarding updates to Teva's order monitoring program); Joseph Tomkiewicz Dep. (11/28/18), Dkt. # 1971-9 at 76:2-79:5, 145:7-146:5, 148:1-155:19.

[231] Exh. 240, TEVA_MDL_A_01454702; Exh 324, TEVA_MDL_A_01464010 at 11.

[232] Exh. 325, ALLERGAN_MDL_02128065; Exh. 326, ALLERGAN_MDL_02166054.

[233] Exh. 327, ALLERGAN_MDL_0164195.

[234] *Id.*

[235] Exh. 328, PAR_OPIOID_MDL_0000002545, Exh. 329, PAR_OPIOID_MDL_0000002546.

[236] Exh. 330, ENDO-HSGAC_0012601.

Distributor Defendants about suspicious order monitoring and requested customer chargeback data that highlighted potentially suspicious customers.[237]

In sum, the Defendants coordinated information about their suspicious order monitoring programs so that they could put into place nearly identical programs that failed to satisfy the anti-diversion requirements. Many of the Defendants have now admitted to breaking the law and violating their CSA duties, including Purdue,[238] Mallinckrodt,[239] Cardinal,[240] McKesson,[241] CVS,[242] and Walgreens.[243]

D. Defendants Used the HDA and NACDS To Protect the Supply Chain

The Manufacturer, Distributor, and Pharmacy Defendants used the HDA (as well as the HDA's work with the PCF) and the NACDS to coordinate a number of joint strategies to protect the supply chain: (1) developing the Industry Compliance Guidelines ("ICGs"); (2) passing legislation that undercut DEA's ability to enforce the CSA; (3) orchestrating meetings with the DEA; (4) negatively

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[237] Exh. 331, PAR_OPIOID_MDL_0000095431.

[238] In 2007, Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers by promoting OxyContin as "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications," paying over $600 million in penalties. *See* Exh. 21, PPLP004496559.

[239] In 2017, Mallinckrodt admitted that "Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters" from the DEA in 2006 and 2007, paying $35 million in penalties. *See* Exh. 332, MNK-T1_0000557100.

[240] In 2012, Cardinal admitted "its due diligence" and "compliance with the 2008 MOA … were inadequate", paying a $44 million dollar fine. *See* Exh. 333, CAH_MDL2804_02465982, 84.

[241] In 2008, McKesson entered into a settlement agreement with the DEA and agreed to pay a $13.5 million fine and make improvements to its controlled substances monitoring practices. *See* Exh. 334, MCKMDL00337001. In 2017, McKesson admitted failing to identify and report suspicious orders in breach of the 2008 MOA and that it "did not identify or report to DEA" orders "which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5)." *See* Exh. 335, MCKMDL00355349.

[242] In 2015 and 2016, CVS admitted that its dispensing practices at pharmacies to which CVS and/or other Defendants distributed breached "compliance obligations under the CSA and its implementing regulations," and in 2017 admitted that certain stores "failed to fulfill certain recordkeeping obligations under the CSA," paying combined fines of $34 million. Exh. 336, CVS-MDLT1-000060796; Exh. 337, CVS-MDLT1-000060805; Ex. 338, CVS-MDLT1 000060856.

[243] In 2013, Walgreens admitted its "suspicious order reporting for distribution … did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007," that its pharmacies had "dispense[d] certain controlled substances" in breach of "compliance obligations under the CSA … and its implementing regulations…," paying an $80 million fine. *See* Exh. 339, WAGMDL00490963.

reporting about DEA to the Government Accountability Office ("GAO")[244]; (5) coordinating *amicus curiae* filings that contained fraudulent statements;[245] (6) market testing and crafting crisis response documents and talking points about the opioid crisis;[246] and (7) coordinating ongoing responses regarding pending litigation.[247]

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[244] HDA reported negatively about the DEA to the GAO on at least two separate occasions. Exh. 340, HDA_MDL_000139905-10; Kelly Dep., Dkt. # 1963-14 at 304:2-312:23; Exh. 341, MCKMDL00612093; Exh. 283, HDS_MDL_00218806; Exh. 342, WAGMDL00330627 at 00330629; Exh. 343, WAGMDL00383683 at 00383684; Exh. 344, HDA_MDL_000107558; Exh. 345, Anda_Opioids_MDL_0000040918; Exh. 346, MCKMDL00538072; Exh. 347, HDA_MDL_000120774 ("I see nothing wrong with letting Smith drug, who is a member of [HDA]'s, know how we're planning to handle it, if they ask and there's an opportunity to do so before hand. I see that as different from the others sharing information who are separate, individual companies. (You don't have to tell GAO if you do.)" followed by the response "Wouldn't that be like lying? Just joking . . ."). HDA members were aware that it participated in discussions about DEA with the GAO and that HDA "explained concerns about the lack of DEA clarification, continued discrepancies between DEA HQ and field offices, along with indifference to industry concerns and unwillingness to meet with stakeholders." Exh. 348, HDA_MDL_000060666; Exh. 349, HDA_MDL_000212238.

[245] HDA prepared and file *amicus curiae* briefs on behalf of the RICO Distributors in: *Cardinal v. Holder*, *Masters Pharmaceuticals, Inc. v. DEA*, and the West Virginia AG litigation.[245] While the *amicus briefs* do not establish liability, they reveal a common purpose advanced by fraud because this brief was requested by HDA's Executive Committee members (Exh. 350, HDA_MDL_000155930 at 000155930-31) and, the HDA falsely represented to the Court that Cardinal Health did not have any input on the *amicus* brief and did not participate in the drafting of that brief. *See* Exh. 351, HDA_MDL_000215212 ("The Executive Committee asked that this be sent to them for approval (or objection) prior to filing. We should also run it by Cardinal's counsel."); Exh. 352, HDA_MDL_000215970 at 000215971 ("Linden Barber and I have reviewed the amicus brief and think it is really quite good. Cardinal Health does, in fact, authorize you to represent that we consent to your motion for leave to file. We make the following suggestion . . ."); Exh. 353, HDA_MDL_000216300 ("This draft brief was reviewed by most of you early last week."). HDA also created talking points demonstrating their support of Cardinal Health (Exh. 354, HDA_MDL_000088099 at 000088100) despite the fact that Cardinal Health eventually admitted that its due diligence practices as required by the 2008 MOU were deficient and did not comply with the law. Exh. 333, CAH_MDL2804_02465982, 84.

[246] HDA retained multiple public relations consultants to modify public perception. Exh. 355, HDA_MDL_000087762 (and attachments); Exh. 356, MCKMDL00586952; Kelly Dep., Dkt. # 1963-14 at 345:18-347:23. This work included research and market-testing messaging to "[i]nform development of research-based positioning, including messages and strategies, that protects and enhances the reputation of the industry." Exh. 357, CAH_MDL2804_01505341; Exh. 355, HDA_MDL_000087762 at 000087722-32; 000087734-54; Exh. 439, HDA_MDL_000087806 at 000087809. HDA members received "key findings" from this research and a "Crisis Playbook" all of which were designed to be used in the event of crises so that the industry could deliver a uniform message. *See* Exh. 358, HDA_MDL_000087734 at 000087737-38; 00087752-83; 00087814 ("Bottom Line: - Clarify what industry already does; - Layer in information about constraints; acknowledge complexities in law enforcement/regulatory collaboration with recommended solutions"); *Id* at Exh. 355, HDA_MDL_000087762 at 000087764-65, 0008777. Significantly, the Crisis Protocol and Playbook both identified "High Risk" "Diversion Issues," including "Distributor Facility Shutdown," "Diversion Lawsuit," and "Congressional Inquiry." *Id.* at 000087774, 00087785. Each of these high risk diversion issues included questions that the members should consider and talking points to address them. *Id.* at 000087787-90, 000087793-94. Evidence indicates that the Defendants were aware of the Crisis Playbook and used it to develop talking points approved and used by the Defendants. Exh. 359, ABDCMDL00278153 (crisis playbook); Exh. 360, CAH_MDL2804_02451868; Exh. 441, CAH_MDL2804_02451869; Exh. 361, ABDCMDL00276898 at 899; Exh. 362, MCKMDL00405144; Exh. 363, ABDCMDL00137132; Exh. 364, MCKMDL00590197; Exh. 365, ABDCMDL00161397; Exh. 366, ABDCMDL00368754.

[247] When the first West Virginia cases pending in this MDL were filed in 2017, Purdue reached out to the Big Three, Johnson & Johnson, Endo, Teva and Allergan requesting a meeting for the purpose of "brainstorming to determine if there is anything" that may be done "with respect to the litigation brought by plaintiff's lawyers and states, cities, counties, and municipalities against the opioid supply chain." Exh. 367, PPLPC020001151103 at 04. The Big Three spoke with

The Defendants' work on the ICGs and their efforts to pass the Marino Bill are two particularly revealing examples of the Defendants working together to protect the supply chain from DEA interference.

1. Defendants Used the HDA and the NACDS to Draft ICGs as a Ruse to Avoid Regulatory Enforcement

Defendants worked together to create the appearance of compliance, while in reality practicing blatant noncompliance. In September 2007, the HDA, the NACDS, and the Manufacturer Defendants attended a DEA conference at which the DEA reminded registrants that not only were they required to report suspicious orders, but also to halt shipments of suspicious orders.[248] Instead of developing policies to improve their compliance with DEA's anti-diversion requirements,[249] HDA took the lead on creating "a multi-pronged strategy with possible approaches for dealing with DEA on the Suspicious Orders."[250] The first prong of this strategy developed into the "'best practices' model for dealing with 'suspicious orders,'"[251] better known as the Industry Compliance Guidelines (ICGs).

The first step was to convince the DEA that industry sought to develop a system by which the industry could feasibly comply with the suspicious order monitoring requirements. To that end, the HDA repeatedly met with the DEA to fully understand the SOM legal requirements, including the requirement to immediately report suspicious orders and then stop their shipment.[252]

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each other first, and then requested that "it would be preferable . . . to have at this meeting Patrick Kelly . . . and his team from our HDA trade group rather than the individual distributor companies." Id. at 03. Similar litigation strategies were shared by individual members of the HAD.

[248] Exh. 235, CAH_MDL_PRIORPROD_DEA07_00877084; Exh. 368, CAH_MDL_PRIORPROD_DEA07_01185382 (Defendants registered for this conference include: Actavis, AmerisourceBergen, Cardinal, Cephalon, H.D. Smith, Henry Schein, JOM Pharmaceutical Services, J&J affiliates, Mallinckrodt, McKesson, Noramco, Purdue Pharma, Qualitest Pharmaceuticals, Walgreens, and Watson.)

[249] Exh. 369, CAH_MDL_PRIOPROD_DEA07_00877471.

[250] Exh. 235, CAH_MDL_PRIORPROD_DEA07_00877084.

[251] Exh. 370, HDA_MDL_000157898.

[252] Kelly Dep., Dkt. # 1963-14 at 80, 88-90, 139; Exh. 371, HDA_MDL_000081363 at 000081364; Exh. 372, CAH_MDL2804_02489197; Exh. 373, CAH_MDL2804_02489160; Exh. 374, CAH_MDL2804_02489199; Exh. 375, CAH_MDL2804_02489188; Exh. 376, CAH_MDL2804_0248191.

The HDA drafted the ICGs purportedly to satisfy those legal requirements.[253] The HDA touted the ICGs as a demonstration of the "industry's tangible efforts" that would produce "[p]ositive PR."[254] In developing the ICGs, the HDA collaborated with the NACDS, noting that "[t]he pharmacy organizations appear very anxious and ready to help us persuade DEA to change their current tactics with respect to licensure suspensions."[255]

The HDA represented to the DEA that it would promote the ICGs to its members and to "allied trade associations," such as "NACDS" and "manufacturer associations (Pharmaceutical Research and Manufacturers Association – PhRMA and the Generic Pharmaceutical Association -- GPHA)"[256] such that the ICGs would serve as an industry-wide standard.[257] HDA scheduled meetings with the NACDS and with manufacture trade group PhRMA as part of its ICG "roll out,"[258] specifically recognizing NACDS and the Pain Care Forum as "external stakeholders" in ICGs.[259]

HDA publicly represented to the DEA that it hoped "that DEA would find the guidelines acceptable as a voluntary 'consent decree,'" and "did not expect these guidelines to result in weakening DEA's enforcement prerogatives."[260] HDA vowed that industry "intended to be part of the solution rather than the problem."[261]

Despite those representations, the HDA failed to disclose to the DEA that it had no authority to force its members to adopt the Guidelines, and it later admitted that it never even intended to create

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[253] *See* Kelly Dep., Dkt. # 1963-14 at 138-39; Exh. 377, HDA_MDL_000141125 (HDA's Executive Committee and Board of Directors approved ICGs in 2008); Exh. 378, HDA_MDL_000217851; Exh. 379, HDA_MDL_000148603.
[254] Exh. 380, HDA_MDL_000213058. The HDA testified before Congress, bragging that "[t]o aid in the development and implementation of [SOM and SOR systems], in 2008 HDMA and its member companies developed [ICGs]… to support distribution industry practices on the evaluation of customer orders for controlled substances and the reporting of 'suspicious' orders to the DEA," assuring Congress that the "ICGs were vetted with the DEA in advance of their publication." Exh. 381, CAH_MDL2804_02376649.
[255] Exh. 370, HDA_MDL_000157898. *See also* Exh. 382, HDA_MDL_000140103; HDA_MDL_000139712.
[256] Exh. 384, HDA_MDL_000084666.
[257] Exh. 385, HSI-MDL-00620224 at 00620225; Exh. 386, HDA_MDL_000143030; Exh. 387, CAH_MDL2804_01521412; Exh. 388, CAH_MDL2804_02489188 at 02489189; Exh. 397, HDA_MDL_000156499.
[258] Exh. 389, HDA_MDL_000142905; Exh. 390, HDA_MDL_000118385; Exh. 391, HDA_MDL_000093755.
[259] Exh. 392, HDA_MDL_000117145; Exh. 393, HDA_MDL_000117158.
[260] Exh. 394, CAH_MDL2804-02489188.
[261] Exh. 385, HSI-MDL-00620224 at 00620225.

an industry standard that distributors would be bound by (as they would be in a consent decree).[262] Moreover, the HDA *knew* that some of its largest members, including AmerisourceBergen and Cardinal Health, would *not* implement the Guidelines, yet did not disclose that fact to the DEA.[263] The explicit "[p]urpose of [the] ICG[s] and DEA [c]ommunications" was to "[h]ead-off' further enforcement or regulatory action."[264]

Indeed, the fact that Defendants never intended the Guidelines to serve as an industry-wide standard (despite its efforts to mislead the DEA otherwise) became abundantly clear when, after the DEA fined Walgreens $80 million for violating the CSA and the Guidelines, HDA stated that NACDS member "Walgreens wasn't an HDA member and was distributing to their own pharmacies, and that the ICG wasn't intended for their purposes."[265] HDA also sought to avoid recognizing any of their members' partial compliance with the ICGs for fear of highlighting that "not all our members are doing what [a supposedly compliant member] does," stating that "[i]f DEA sees this, which they are likely to at some point, they may question why aren't all our members doing it…."[266] Eventually, even the HDA itself admitted that the Guidelines were "never intended to constitute a 'standard'"[267] and took them down from their website.[268]

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[262] Kelly Dep., Dkt. # 1963-14 at 241:13-242:8 (HDA cannot make any entity comply with the guidelines); *Id.* at 248-49 (HDA did not ask whether Distributor members adopted Guidelines); Exh. 395, HDA_MDL_000080421; Exh. 388, CAH_MDL2804_02489188 at 02489189; Exh. 412, HDA_MDL_000155886 at 000155936; Exh. 350, HDA_MDL_000155930 at 000155936; *see also* Exh. 396, HDA_MDL_000081415.

[263] Exh. 385, HSI-MDL-00620224 at 00620225; Exh. 386, HDA_MDL_000143030; Exh. 387, CAH_MDL2804_01521412; Exh. 388, CAH_MDL2804_02489188 at 02489189; Exh. 397, HDA_MDL_000156499-01 ("Since ABC has an agreement with DEA, it does not matter what best practices HMDA develops because ABC must adhere to its written agreement with DEA. I assume Cardinal will be in the same boat.").

[264] Exh. 398, HDA_MDL_000145918 at 000145932.

[265] Exh. 395, HDA_MDL_000080421.

[266] Exh. 395, HDA_MDL_000080421.

[267] Exh. 350, HDA_MDL_000155930 at 000155936; Exh. 399, HDA_MDL_000081415.

[268] Exh. 400, HSI-MDL-00214816.

2. Defendants Used the HDA to Support the Marino Bill, Which Limited DEA's Enforcement Authority

The Defendants engaged in additional coordinated efforts to stymie the DEA's legitimate law enforcement efforts. Defendants shared the goal, articulated by the HDA, of "develop[ing] a comprehensive DEA strategy" to avoid enforcement actions being taken against their members.[269] Defendants carried out their coordinated strategy to weaken the DEA's enforcement capabilities in part through the Marino Bill.

Shortly after the DEA suspended Cardinal's Lakeland facility, the HDA began considering a legislative strategy for "alter[ing] the present direction DEA is taking with respect to suspicious order monitoring."[270] At the time, the CSA allowed the DEA to immediately suspend a registration, and to keep it suspended during an administrative revocation proceeding, in any case "where [the DEA] finds that there is an imminent danger to the public health or safety."[271] That powerful tool was regularly used by the DEA to compel the Defendants' compliance with their CSA duties.[272]

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[269] Exh. 401, CAH_MDL_PRIORPROD_DEA07_00877471; Kelly Dep., Dkt. # 1963-14 at 62.

[270] Exh. 402, HDA_MDL_000215234.

[271] Joseph Rannazzisi Dep. (05/15/19), Dkt. # at 590:21-591:1.

[272] Exh. 219, ABDCMDL00279854 (June 22, 2007 AmerisourceBergen Settlement and Release Agreement); CAH_MDL_PRIORPROD_DEA12_00005805 (December 7, 2007, Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone); Exh. 403, CAH_MDL_PRIORPROD_DEA12_00013041 (November 28, 2007, Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center, which suspended their DEA registration for failure to maintain effective controls against diversion of hydrocodone); Exh. 404, CAH_MDL_PRIORPROD_DEA12_00015225 (December 7, 2007, Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone); Exh. 405, CAH_MDL2804_01458088 (January 30, 2008, Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone.); Exh. 406, CAH_MDL_PRIORPROD_DEA12_00006089 (February 2, 2012, Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone); Exh. 407, CAH_MDL2804_02129383 (May 14, 2012, Cardinal Health Administrative Memorandum of Agreement with the DEA, which, among other things, stipulated that its compliance with the terms of the 2008 MOA were inadequate in certain respects and that its Lakeland, Florida Distribution Center's DEA registration would be suspended for two years.); Exh. 408, CAH_MDL2804_03361833 (September 13, 2012 Order to Show Cause and Immediate Suspension of Registration to Walgreens" Jupiter, Florida Distribution Center); Exh. 339, WAGMDL00490963 (June 11, 2013 Settlement and Memorandum of Agreement with Walgreen Co.); Exh. 336, CVS-MDLT1-000060796 (May 12, 2015, Settlement Agreement among the United States and the DEA and CVS Health and all of its subsidiaries and affiliates, covered CVS's "Florida Distribution Center[s] failure to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 U.S.C. §823(e)" and failure to timely detect and report suspicious orders of controlled substances.)

Around that time, the HDA met with outside counsel to obtain recommendations on "potential actions the [HDA] and the industry may consider in an effort to alter the present direct DEA is taking with respect to suspicious order monitoring."[273] Notably, the lawyers "felt that we may be better off averting DEA actions ***by taking even stronger compliance measures***." [274] The Defendants rejected that advice.

Instead, HDA's focus shifted to "other areas of attack" following a meeting that included Cardinal Health, AmerisourceBergen, McKesson, Mutual Drug and J.M. Smith along with HDA staff.[275] In December 2013, the HDA identified the "issu[ance of a] statement of support for Marino/Blackburn legislation," as a strategy for dealing with the DEA's approach to diversion.[276] That draft legislation included a new statutory definition of "imminent danger to the public health or safety" and "would allow DEA registrants the opportunity to submit a corrective action plan to address specific concerns that could otherwise lead to the suspension or revocation of a registration."[277] That is, the draft legislation stripped the DEA of the ability to issue an immediate suspension order against a drug manufacturer or distributor whose unlawful conduct poses an imminent danger to the community. Purdue and its outside lobbyist were the source of the new "imminent danger to the public health or safety" language.[278]

In 2014, when the DEA was investigating various distributors, the Distributor and Pharmacy Defendants, through the HDA and NACDS, turned to the Pain Care Forum to coordinate support for passing the Marino Bill.[279] Non-industry Pain Care Forum members signed letters that the HDA

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[273] Exh. 402, HDA_MDL_000215234.
[274] *Id.* at 000215235 (emphasis added).
[275] Exh. 409, HDS_MDL_00395536; Exh. 410, CAH_MDL2804_01110712; *see also* Exh. 411, HDA_MDL_000082152; Exh. 412, HDA_MDL_000155886; Exh. 350, HDA_MDL_000155930 at 000155935-36.
[276] Exh. 410, CAH_MDL2804_01110712 at 01110714.
[277] *Id.*
[278] Rosen Dep., Dkt. # 1970-10 at 270-72, 299-300; *see also* Exh. 413, MCKMDL00651560.
[279] Exh. 414, PPLPC018000962773; Exh. 415, PPLP004267695; *See also* Exh. 416, PPLPC017000518587 (In an email, Burt Rosen stated: "Suspect we will discuss at Pcf as pharmacy and wholesaler a (sic) are behind the proposal"). Exh. 417, HDA_MDL_000214864; Exh. 418, HDA_MDL_000081283; Exh. 419, HDA_MDL_000081651.

drafted in support of the Bill.[280] Thus, Defendants used their memberships in multiple organizations to make it appear that the Marino Bill had widespread support from neutral third parties. One such group was the Alliance to Prevent the Abuse of Medicines, whose members included CVS, Cardinal Health, Teva, and the HDA (as an advisory member).[281] When the Alliance was asked to sign on to a 2014 letter of support it was "signed by the Alliance, ***not the individual members***."[282] The final letter that was sent to Senators Hatch and Whitehouse was signed by the members of the Pain Care Forum as well as the Alliance, the NACDS, American Academy of Pain Management, and U.S. Pain Foundation.[283]

HDA, NACDS, and manufacturers, including Purdue and Endo, worked together to influence the language in the bill to make it most favorable for them and ineffective for the DEA.[284] Defendants sought to avoid any language that "codifies DEA's current approach to immediate suspensions."[285]

[280] [Exh. 420, PPLP004267618 (Jan. 22, 2015 email from HDMA to PCF); Exh. 415, PPLP004267695.] Exh. 425, CVS-MDLT1-000093530-00009353.
[281] Exh. 421, CVS-MDLT1-000079145; Exh. 422, CVS-MDLT1-000079146 at 000079152-000079153; Exh. 423, CVS-MDLT1-000103561 at 000103562-63; Exh. 424, CVS-MDLT1-000103494 at 499.
[282] Exh. 425, CVS-MDLT1-000093530-000093531; *see also* Exh. 418, HDA_MDL_000081283-84; Exh. 415, PPLP004267695; Exh. 420, PPLP004267618.
[283] Exh. 419, HDA_MDL_000081651 at HDA_MDL_000081653-54.
[284] Exh. 426, CAH_MDL2804_02471125; Exh. 427, CAH_MDL2804_02471084; Exh. 428, ABDCMDL00273963; Exh. 429, CAH_MDL2804_02467634.
[285] Exh. 427, CAH_MDL2804_02471084 at 86.

The DEA opposed the law because it limited its ability to suspend registrations as a critical part of its enforcement authority.[286] The HDA supported it for this exact reason.[287] HDA's Executive Committee directed the HDA to: "exhaust all efforts to secure passage of [the Marino Bill]."[288]

The enacted version of the Marino Bill became law with a new statutory definition of "imminent danger to the public health or safety."[289] The law made it next to impossible for the DEA to impose an immediate suspension on drug distributors or manufacturers.[290] Purdue touted its role in changing the DEA's enforcement powers, stating that "Purdue was very active in influencing the ultimate definition of an 'imminent danger to the public health or safety," and worked with the HDMA and NACDS for "two years" to achieve this result.[291] The Pain Care Forum did not publicly acknowledge its role in passing the Marino Bill.[292]

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[286] Exh. 430, MCKMDL00651560 at 00651561-63.

[287] In later conversations, HDA could not "reference any blanket letter of support that [it] had issued on Opioid abuse issues in the past outside of HDA's support for CARA at the federal level." Exh. 431 HDA_MDL_000214979. "Bottom line is," HDA could not "recall any time that [it] had openly and public supported an opioid abuse prevention measure." *Id.*; *see also* Kelly Dep., Dkt. # 1963-14 at Exh. 39; Kelly Dep., Dkt. # 1963-14 at 356:1-2; 358:6-12; Exh. 413, MCKMDL00651560 at 0065156217-00208-F (DEA/DOJ Memos noting concern about the bill); PL 114-145, 130 Stat 354 amended multiple sections of the CSA including, relevant here, 21 U.S.C. 824(d)(2). Notably, the revisions did not include DEA's requested changes. 21 U.S.C. § 824(d)(2). *See also* Dep., Dkt. # 1963-14 at 364:3-368:24; *see also id.* at 368:9-24.

> Q. Did the final bill have the definition of imminent danger?
> A. It did.
> Q. Did it have the corrective action plan?
> A. It did.
> Q. Did it mandate the DEA to participate in a stakeholder working group?
> A. It Did.
> Q. Did it add the "consistent with the public health and safety" language?
> A. I don't know if the specific language was in there. I'm happy to look at the final version of the bill and tell you, yes.

[288] Exh. 350, HDA_MDL_000155930 at 000155941. During deposition, HDA's witness clarified that S.483 (quoted in the original document cited herein) was the final version of the Marino Blackburn bill "that got passed by the Senate and approved unanimously both -- in both chambers and signed by President Obama." Kelly Dep., Dkt. # 1963-14 at 369:7-370:12.

[289] Exh. 432, HDA_MDL_000134198.

[290] *See* Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 Marq. L. Rev. 333, 347 (2017); [Exh. 433, PPLPC017000798471 at 72-76.]

[291] Exh. 434, PPLPC017000701492.

[292] Purdue was also providing "final feedback" to PhRMA's Federal Steering Committee about the Marino Bill and other legislation "so they may forward any concerns or sticking points to committee staff." PPLPC017000681743 at 44. Once the true effect of the Marino Bill became public, however, PhRMA publicly denied supporting the Marino Bill and even had the Washington Post correct a story reporting that PhRMA supported the Marino Bill. Exh. 435, HDA_MDL_000212533.

Thus, the passage of the Marino Bill highlights coordinated efforts by the Defendants to further their common purpose to thwart DEA's legitimate law enforcement efforts to prevent diversion of dangerous drugs to protect the public.

3. Defendants Used the HDA to Hire Public Relations Consultants to Respond to the Opioid Crisis

The HDA retained multiple public relations consultants – including the RAND Corporation, APCO, and Reservoir - to study public perception of the opioid crisis and recommend an effective coordinated approach.[293] APCO's work for HDA included extensive research on effective messaging "that protects and enhances the reputation of the industry."[294] The research was used to create uniform talking points about the industry's response to diversion. APCO's "Key Findings" confirmed that the industry's "clear message" regarding their "limited access to data from DEA" created "doubt about regulators/enforcers," but that using the DEA to shirk responsibility was not enough.[295] APCO recommended that: "HDMA and the industry accept responsibility for addressing the diversion issue" and that the "industry should reinforce [that] it takes the issues seriously and will go beyond what is currently expected by law to combat diversion and drug misuse."[296] APCO further suggested that "the industry" "should be more proactive" in communicating what they did to report "distribution anomalies."[297]

APCO also created a "Crisis Protocol" and a "Crisis Playbook" to coordinate "Core Messaging" regarding diversion crises that HDA and its members could use.[298] Significantly, both the

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[293] Exh. 436, HDA_MDL_000156420; Exh. 437, CAH_MDL2804_01110774 at 776; Exh. 438, ABDCMDL00375197; Exh. 355, HDA_MDL_000087762 (and attachments); Exh. 356, MCKMDL00586952; Kelly Dep., Dkt. # 1963-14 at 345:18-347:23.

[294] Exh. 357, CAH_MDL2804_01505341; Exh. 355, HDA_MDL_000087762 at 000087722-32; 000087734-54; Exh. 439, HDA_MDL_000087806 at 000087809.

[295] Exh. 358, HDA_MDL_000087734 at 000087752; HDA_MDL_000087734 at 000087737-38.

[296] *Id.* at 000087753; *see also* 000087814: ("Bottom Line: - Clarify what industry already does; - Layer in information about constraints; acknowledge complexities in law enforcement/regulatory collaboration with recommended solutions").

[297] Exh. 358, HDA_MDL_000087734 at 000087753.

[298] *Id* at Exh. 355, HDA_MDL_000087762 at 000087764-65, 000087774; 0008777. The "Crisis Protocol identifies itself as a tool for "Scenario Planning and Messaging." *Id.* The Crisis Playbook similarly identifies itself as an "Interactive Guide to Crisis Communications." Exh. 359, ABDCMDL00278153; Exh. 440, ABDCMDL00278154.

Crisis Protocol and Playbook devote an entire section to "High Risk" "Diversion Issues," including: "Scenario 1: Distributor Facility Shutdown;" "Scenario 2: Diversion Lawsuit;" and "Scenario 4: Congressional Inquiry."[299] Each high risk scenario comes with a list of "Key Considerations/Questions," a "Statement," and "Tough Q&A" so the members could demonstrate concerns about compliance and have uniform canned responses.[300] Evidence indicates that HDA and its members[301] used the Crisis Playbook.[302]

Conversely, when RAND would not give HDA editorial control over a study related to drug diversion and regulation,[303] the project was scrapped.[304] RAND indicated that "in order to make sure that the recommendations in this final report are viewed as truly objective and unbiased, given there might be a perception of bias in light of the funding source," it needed to "vet the draft final report with experts from industry, law enforcement and regulatory authorities."[305] But, HDA expressed its concern about "our ability to control content" and "when we can stop the report from being published assuming it reaches conclusions not favorable to our industry."[306]

Additional examples of HDA coordination occurred when HDA sought further advice from counsel who advised on the ICGs and formed a "Drug Diversion/DEA Strategy Task Force" to discuss "development of potential strategies that [HDA] could employ to begin to alter the dialogue and outcomes of the drug diversion problem."[307] These actions occurred immediately after DEA

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[299] Exh. 355, HDA_MDL_000087762 at 000087785; Exh. 440, ABDCMDL00278154 at 00278177.
[300] Exh. 355, HDA_MDL_000087762 at 000087786-90, 000087793-94; Exh. 440, ABDCMDL00278154 at 00278178-82, 00278186-87.
[301] Exh. 359, ABDCMDL00278153.
[302] Exh. 360, CAH_MDL2804_02451868; Exh. 441, CAH_MDL2804_02451869; Exh. 361, ABDCMDL00276898 at 899; Exh. 362, MCKMDL00405144; Exh. 363, ABDCMDL00137132; Exh. 364, MCKMDL00590197; Exh. 365, ABDCMDL00161397; Exh. 366, ABDCMDL00368754. Notably, HDA began creating talking points for its members and employees to use well before HDA hired APCO, but they've always served the same purpose. Exh. 442, HDS_MDL_00119227; Exh. 443, MCKMDL00612053-055; Exh. 444, CAH_MDL2804_01430173-177; Exh. 445, ABDCMDL00264801 at 802.
[303] Exh. 446, HDA_MDL_000087621; Exh. 447, HDA_MDL_000087598; *see also* Exh. 449, HDA_MDL_000156419.
[304] Exh. 450, HDA_MDL_000160016 at HDA_MDL_000160026.
[305] Exh. 446, HDA_MDL_000087621.
[306] Exh. 447, HDA_MDL_000087598.
[307] Exh. 451, HDA_MDL_000081364 at 00081368; Exh. 452, CAH_MDL2804_01110752.

suspended Cardinal Health's registration for the second time.[308] So, HDA met "with W&C (Barnett and Cooper) on DEA strategic options," which meeting resulted in HDA's President John Gray "send[ing a] memo to ExComm summarizing DEA strategic options."[309]

4. Pharmacies and Distributors Coordinated through HDA and NACDS to Invalidate Enforcement Actions

The HDA also filed amicus briefs seeking to invalidate DEA enforcement actions in both *Cardinal v. Holder* (concerning revocation of a Cardinal distribution license) and then jointly with the NACDS in *Masters Pharmaceutical* (concerning the "do not ship" duty).[310] In June 2012, the HDA Executive Committee "expressed satisfaction with HDMA's role" in effectively delaying DEA compliance by "supporting industry efforts to gain greater clarity from DEA as to what is needed to comply with suspicious order monitoring requirements," as Cardinal "thanked Executive Committee members and HDMA for its support during its litigation with DEA."[311]

5. Pharmacies and Distributors Used the HDA and NACDS to Fight Stricter Controls for Hydrocodone Combination Products (HCPs)

Defendants also engaged in a united approach to "take on [the] DEA" and "challenge" the DEA's attempt to reschedule HCPs from Schedule III to Schedule II opioids and "delay" implementation of more stringent HCP regulations.[312] NACDS reached out to the PCF to create a Task Force, and included HDA representatives as well as numerous manufacturers.[313] The NACDS collaborated with the PCF "communications working group" and sent statements to media outlets claiming the rescheduling would "negatively impact access to needed medications for those who suffer

[308] Exh. 451, HDA_MDL_000081364 at 00081368.
[309] *Id.*; Exh. 402, HDA_MDL_000215234.
[310] Exh. 453, HDA_MDL_000140781; Exh. 454, HDA_MDL_000212400; Exh. 455, CAH_MDL_PRIORPROD_DEA12_00013512.
[311] Exh. 456, HDA_MDL_000156141 at 000156156.
[312] Exh. 457, ABDCMDL00277691; Exh. 456, HDA_MDL_000156141 at 000156156; Exh. 458, CVS-MDLT1-000106758.
[313] Exh. 459, PPLP004018429.

from chronic pain."[314] NACDS and HDA also focused on the "increased costs" to pharmacies and distribution warehouses,[315] pulling cost information from members.[316] The NACDS encouraged members to oppose HCP rescheduling, despite admitting the prescription drug abuse is "so bad" in certain states that legislators feel they must "do something."[317] Defendants knew rescheduling from Schedule III to Schedule II would "tighten controls" on HCPs and reduce their sales.[318]

6. Pharmacies and Distributors Used HDA and NACDS to Oppose Other Legislation

In August 2011, the NACDS and HDA and GPHA worked together on a joint letter opposing DEA fee increases for registrants that were intended to fund the "hir[ing of] more agents and do[ing] more inspections."[319] In 2012, the NACDS sought to restrict required use of available dispensing data in Ohio.[320] In 2016, the NACDS Policy Council discussed ongoing efforts to shape opioid legislation, including their success in removing a requirement that pharmacists have to check their state drug monitoring program before filling controlled prescriptions.[321] NACDS fought regulatory efforts to require Defendants to use available dispensing related data and red flags to prevent diversion, opposing "recent DEA actions in which DEA is expecting pharmacists to be enforcement agents with respect to prescriptions for pain medications."[322] In 2017, through the Anti-Diversion Industry Working Group, Defendants sought to rewrite and invalidate the longstanding tools that DEA had been using to force Distributors and Pharmacy Distributors to comply with their CSA obligations.[323] In March 2018, the HDA, NACDS, and Walgreens discussed Ohio licensure and suspicious order

[314] Exh. 10, CVS-MDLT1-000121577 (NACDS committee included CVS, Walgreens, McKesson, Rite Aid, and HBC/Giant Eagle).
[315] Exh. 460, WAGMDL00614056.
[316] *See, e.g.*, Exh. 461, WAGMDL00075673.
[317] Exh. 462, WAGMDL00614060.
[318] Exh. 463, JAN-MS-00942354 (rescheduling will "reshape" business of hydrocodone sellers and "have an impact on demand" because "doctors don't like to prescribe Sch II" as much as schedule III opioids due to stricter prescribing requirements).
[319] Exh. 464, CAH_MDL2804_00899796; Exh. 465, CAH_MDL2804_00899820; Exh. 466, HDS_MDL_00364536.
[320] Exh. 467, WAGMDL00580486.
[321] Exh. 468, WAGMDL00605718 (including Walgreens, CVS, Cardinal, Walmart, McKesson, Rite Aid, and AmerisourceBergen).
[322] Exh. 469, WAGMDL00638068.
[323] Exh. 470, CAH_MDL2804_03192350; Exh. 471, CAH_MDL2804_03192349.

rules, noting that they shared many "heartburn issues," including fighting requirements for on-site due-diligence visits to pharmacy stores.[324] NACDS, Rite Aid, and Walgreens also sought to help their "business partners HDA" "kill" other controlled substance legislation.[325]

7. Pharmacies and Distributors Used the HDA and NACDS to Circumvent the DEA

Defendants worked through NACDS and HDA in many additional ways to circumvent their CSA obligations and create a false appearance of compliance. To that end, the NACDS and HDA engaged in a "coalition" on controlled substances, which discussed "ensur[ing] that any imposed restrictions regarding the continued distribution of controlled substances are not performed in an overly broad manner."[326] HDA maintained a goal of "help[ing] ease DEA pressure on our members for SO monitoring" and getting the DEA to "let up a little," and viewed "protect[ing] the industry's interests and prevent[ing] undue regulatory impact and reputational harm" as one of the roles of distributors in the "RX Abuse epidemic."[327] NACDS similarly committed to "engag[ing] with" HDA to "develop and pursue solutions" regarding "pain management" and "drug abuse," with a focus on "seek[ing] to require DEA to consider and balance the impacts of its enforcement actions against the negative impacts on public health and patient care" – *i.e.* the disruption of the Defendants' sales and profit stream.[328] NACDS and HDA sought to slow down and impede DEA enforcement activities by requiring the DEA to "work with the FDA on all drug diversion issues," claiming that the DEA's diversion enforcement activities – including "clos[ing] drug distribution centers and pharmacies" and "actions against pharmacies" – were "leading to patients not being able to receive their medications" (*i.e.*, industry code for impeding sales).[329]

[324] Exh. 472, HDA_MDL_000094993.
[325] Exh. 473, Rite_Aid_OMDL_0015830; Exh. 474, CAH_MDL2804_01346988.
[326] Exh. 475, ABDCMDL00277095.
[327] Exh. 476, HDA_MDL_000216988; Exh. 477, HDA_MDL_000082172.
[328] Exh. 478, CAH_MDL2804_02168107.
[329] Exh. 479, WAGMDL00638071 (emphasis original); Exh. 480, HDA_MDL_000156643.

In March and May 2012, NACDS and HDA each met regarding "Drug Diversion / DEA," with HDA touting its "ongoing efforts with DEA on behalf of members," including the amicus brief HDA filed to unseat the DEA's enforcement action against Cardinal.[330] NACDS and HDA agreed that the Pharmacies should "be more aggressive," and "lead the charge" with respect to certain DEA issues.[331] NACDS members coordinated regarding pharmacy diversion "DEA red flags" through a "DEA Compliance Workgroup," seeking to focus on keeping the drugs flowing while promoting optics, noting that "policies that are too prescriptive … should not be included in the code" and citing meeting "pain control needs of patients" as a "Guiding Principle."[332] Defendants further used an NACDS "Pharmacy Compliance Roundtable" to discuss avoiding criminal and civil liability for issues related to controlled substances, SOM, and diversion.[333]

In February 2014, the HDA recommended continuing to "partner with other supply chain shareholder groups" and to "[d]evelop … solutions to the [DEA] enforcement issues."[334] In 2014, when the HDA discussed a plan involving NACDS and PhRMA to develop a "Red Flags" guidance document for prescription opioids (much like the ICGs), HDA noted that the "subtext strategy … [was to] keep the DEA at bay."[335]

Defendants further used HDA and NACDS to recommend and pursue strategies with the best public relations appearance but the least potential to require Defendants to slow down their sales and distribution. For example, in September 2012 HDA reviewed and ranked various "CS Abuse and Diversion Regulatory Options," ranking low any that would require increased compliance and ranking

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330 Exh. 481, CAH_MDL2804_02544098 at May 15 2012 minutes of GPPC (including overlapping NACDS leadership (such as Cardinal and AmerisourceBergen); Exh. 482, CAH_MDL2804_00918232 (including CVS, Walgreens, McKesson, Cardinal, AmerisourceBergen, Rite Aid, and Walmart).
331 Exh. 483, WAGMDL00642582.
332 Exh. 484, CAH_MDL2804_02933681; Exh. 485, CAH_MDL2804_02933683; Exh. 486, CAH_MDL2804_02933698
333 Exh. 487, ABDCMDL00400378; Exh. 488, ABDCMDL00400380 (including Walmart, Rite Aid, Walgreens, Cardinal, and AmerisourceBergen).
334 Exh. 456, HDA_MDL_000156141 at Feb 2014 EC Minutes
335 Exh. 489, HDA_MDL_000087636; Exh. 490, HDA_MDL_000080017.

high any that would generate positive PR or reduce DEA enforcement capabilities.[336] Similarly, in the context of discussing a "DEA Data Solution," the NACDS admitted that the broad scope of prescribing data available covered 94% of manufacturers and wholesalers and could be used to "identify potentially bad prescribers and pharmacies."[337] However, defendants declined to proactively incorporate these strategies.

In April 2012, the HDA Executive Committee discussed "coordinat[ed] efforts with NACDS" and their "stepp[ed] up" public relations strategies regarding purported CSA compliance.[338] In May 2012, the NACDS formed a Policy Council "Task Group" to "discuss issues and develop strategies" concerning "ongoing problems that NACDS members are having with DEA enforcement actions," through which it sought to influence the government and media,[339] set meetings with legislators seeking to "address the problems with DEA actions,"[340] and "collaborate with, and support others' efforts" including HDA.[341] In August 2012, the HDA formed a companion "HDMA Controlled Substances Abuse Task Force,"[342] to 'continue to work with…NACDS [] on initiatives related to prescription drug abuse and diversion and work towards consensus-based solutions…."[343] The "consensus-based solutions" included a coordinated public relations strategy for beating back "the 'drumbeat' regarding use and abuse of controlled substance [which] is loud, painful and consistent," including that "the prescription drug abuse is considered an 'epidemic' by the … (CDC)… [and that] the … (DEA) considers prescription drug abuse a top enforcement priority," and also seeking to characterize DEA enforcement actions against distributors as "misleading"[344]

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[336] Exh. 491, HDA_MDL_000067165 at 67179.
[337] Exh. 492, WAGMDL00331103; Exh. 493, WAGMDL00331107.
[338] Exh. 456, HDA_MDL_000156141 at April 6, 2012 EC Minutes (including AmerisourceBergen, Cardinal, McKesson, and H.D. Smith).
[339] Exh. 494, CAH_MDL2804_02168066; Exh. 495, CAH_MDL2804_01087928.
[340] Exh. 496, CAH_MDL2804_00876511.
[341] Exh. 497, CAH_MDL2804_02168079 (Policy counsel discussing this issue included CVS, McKesson, AmerisourceBergen, Rite Aid, Walmart, Walgreens, and Cardinal).
[342] Exh. 498, HDA_MDL_000088117.
[343] Exh. 498, HDA_MDL_000088117.
[344] Exh. 499, ABDCMDL00284760.

E. The PCF Reveals Further Coordination to Protect the Opioid Supply Chain

As previously discussed, the PCF was an important forum for the Manufacturer Defendants to spread their fraudulent marketing messages.[345] By 2006, the PCF had expanded its mission: "we should think of a DEA Strategy that [the DEA] could support. We have all labored to find the MOST potent strategy to change DEA policy and activities."[346] The PCF's interest at this time was to "get people who know the DEA, how they work, who they answer to, their vulnerabilities, etc in a room to help APF devise a plan to successfully change DEA policy/actions regarding prescription pain medicines."[347] Stated more poignantly in 2007, the goal was to "Curtail DEA / law enforcement interference."[348]

While the PCF was active on issues related to suspicious order monitoring, the interaction of the HDA and the PCF on supply chain issues provides some of the most compelling evidence of an ongoing enterprise with a common purpose. Specifically, in 2008, PCF members were aware of the HDA's work on suspicious order monitoring and HDA's objection to DEA's Distributor Initiative.[349] Evidence confirms that HDA joined[350] and eventually presented to the PCF about its ICGs[351] and

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[345] Exh. 500, JAN-MS-00934868-69. Notably, prior to the formation of the PCF the front groups controlled by the Manufacturer Defendants appeared to "only advocate for the industry's position when they shared an interest on an issue." Exh. 501, JAN-MS-02494553. On February 9, 2001, the New York Times published an article entitled "Cancer Painkillers Pose New Abuse Threat" (available at https://www.nytimes.com/2001/02/09/us/cancer-painkillers-powe-new-abuse-threat.html) that resulted in a galvanizing effort between Purdue and Janssen and others to "try to help deal with this media blitz and **protect the pain movement**." Exh. 23, PPLPC037000007677. Very quickly thereafter, Dr. Foley would advocate that the industry "speak with ONE VOICE" and "come together as a sort of cohesive voice." Exh. 502, JAN-MS-00313199-202; Exh. 41, PPLPC037000008901-902.

[346] Exh. 503, CHI_000253579 at 000253580. Will Rowe was the President of the American Pain Foundation. Tamara Sloan Anderson was an administration for the American Pain Foundation and the PCF. And, Mary Bennett, was a Director at the American Pain Foundation. These individuals, all recipients of CHI_000253579 were all instrumental in the APF's work facilitating the creation of the PCF. *See also* JAN-MS-000934869 ("Will Rowe, Executive Director of the American Pain Foundation . . . will serve as the initial Executive Committee.").

[347] Exh. 504, PPLPC049000015432 at 33.

[348] Exh. 505, CHI_000261967-891.

[349] Exh. 506, ENDO-OPIOID_MDL-06083983. PCF members stated that "[t]his is worth looking at as it represents the continuing 'creep' of DEA into activities that contribute to the overall chilling effect of prescribing pain medicines." *Id.*

[350] Exh. 507, HDA_MDL_000190452 ("HDMA in March 2008 joined the Pain Care Forum."); *See also*, Exh. 508, Anda_Opioids_MDL_0001230959; Kelly Dep., Dkt. # 1963-14 at 226:11-226:14; Exh. 509, PPLPC019000221695.

[351] Exh. 510, PPLPC004000183430; Exh. 511, PPLP004067096; Exh. 393, HDA_MDL_000117158 at HDA_MDL_000117172; Kelly Dep., Dkt. # 1963-14 at 250:7- 251:5.

became "very active in the Pain Care Forum."[352] And, even though HDA attempted to remove itself from the list of PCF "Participating Companies and Organizations," HDA wanted "to remain on the mail distribution list and participate in meetings if permitted."[353]

The PCF and the HDA worked together on many issues, including the ICGs,[354] hydrocodone rescheduling,[355] the creation of Risk Evaluation and Mitigation Strategies (REMs) for prescription opioids,[356] issues related to diversion and suspicious order monitoring,[357] and passage of the Marino bill.[358]

F. Defendants Coordinated to Keep the Flood Gates Open

In furtherance of the conspiracy, Defendants worked together to evade the trip wires that were supposed to shut down supply to prevent diversion. The interactions between the Distributor and Pharmacy Defendants are especially telling. Though information sharing, Distributor and Pharmacy Defendants effectively gamed the system by adjusting the thresholds that were the basis for SOM triggers, manipulating the timing of orders, and directing whether orders were placed to an internal or external supplier, in order to avoid red flags and skirt compliance. Moreover, despite the fact that many of the Defendants were competitors, they helped each other hide noncompliance from the DEA.

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[352] Exh. 512, PPLP003985564; Exh. 513, PPLP004321196; Exh. 514, PPLPC018001397464; Exh 515, PPLP004023440. Notably, ABDC sought meetings with Purdue about the PCF about joining, but it appears that those meetings were also geared towards supporting the HDA's eventual membership. Exh. 516, PPLP004301234 (In 2008 Rita Norton of AmerisourceBergen has a meeting with Burt Rosen to discuss "how to work with the Coalition. Very low key.") McKesson also eventually joined the HDA in its individual capacity aside from its representation through the HDA. Exh. 517, PPLPC004266075 (2016 email from Burt Rosen to Pete Slone admitting McKesson to the Pain Care Forum).

[353] Exh. 514, PPLPC018001397464.

[354] Exh. 518, PPLP004301330; Kelly Dep., Dkt. # 1963-14 at 250:7-251:5.

[355] *See supra*, pp. 53-54. Exh. 519, MCKMDL00545288; Exh. 520, PPLPC020000627451; Exh. 521, CAH_MDL2804_00807654; Exh. 522, TEVA_MDL_A_04209613; Exh. 523, HDA_MDL_000006613.

[356] *See supra*, pp. 22-24. Exh. 524, PPLPC019000247205; Exh. 525, PPLPC004000191543; Exh. 526, PPLPC019000264208; Exh. 443, MCKMDL00612053.

[357] *See supra*, at pp. 55-58. Exh. 527, PPLPC018000239672; Exh. 510, PPLPC004000183430.

[358] *See supra*, at pp. 47-51. Exh. 420, PPLP004267618; Exh. 528, Anda_Opioids_MDL_0000098078 ("HDMA has been working for the past few weeks to identify additional supportive groups for the Ensuring Patient Access and Drug Enforcement Act of 2015. HDMA worked through the Pain Care Forum to encourage a group of sixteen patient and pharmacy groups to send a letter of support today to Congressmen Marino (R-Pa.), Blackburn (R-Tenn.), Welch (D-Vt.) and Chu (D-Calif.)").

Because the Distributor Defendants often served as secondary suppliers to distribute opioids to the same chain pharmacy stores also being supplied by the Pharmacy Defendants, Defendants knew without question they were supplying the same customers. The Pharmacy and Distributor Defendants had the ability to see all opioids being supplied to the pharmacy stores they were jointly supplying.[359] The Pharmacy Defendants in particular were in possession of the full range of distribution information to their stores due to their vertically integrated structure. However, instead of using their data to institute more effective controls against diversion, these Defendants actively shielded each other from DEA attention to protect the flow of drugs and their sales. For example, in 2008, Cardinal Health represented to the DEA that "CVS [and] Walgreens, … all of which are large, national or regional chains … pose no threat of diversion due to their sophisticated anti-diversion systems."[360] In reality, neither CVS nor Walgreens operated an effective SOM system, and both were heavily sanctioned by the DEA as the opioid spike in Florida made their SOMs failures impossible to ignore.[361] Cardinal Health acknowledged its preferential treatment when Walgreens later hired AmerisourceBergen as its exclusive supplier, stating "we bailed you guys out when you had your [DEA] issues," and asked Walgreens not to discuss Cardinal Health's own regulatory violations in the press.[362]

The Distributor Defendants made it clear to the Pharmacy Defendants that their SOM programs would be nominal and that they would work with pharmacies to prevent DEA intrusion. For example, in 2008, Cardinal Health prepared talking points for a NACDS Conference about its planned retail chain SOM program, making it clear that the program would "minimize the disruption" to retail chains and that they would "work together" with the pharmacies " to ensure that our

[359] Exh. 529, CVS-MDLT1-000078102; Exh. 530, WAGMDL00325170; Exh. 531, WAGMDL00325172 (incorporating secondary Distributor orders into Walgreens SOM program); Exh. 532, WAGMDL00316776 ("data mining is done across Walgreens retail pharmacies to determine the maximum about that a pharmacy should be allowed to receive"; Exh. 533, WAGMDL00104076 (Walgreens "Unlocks visibility using data mining to … controlled substance distribution for the enterprise").
[360] Exh. 534, CAH_MDL2804_01376788.
[361] *See infra*, pp.64-69.
[362] Exh. 535, WAGMDL00746694.

Suspicious Order Monitoring program for retail chains does not interrupt" business."[363] Cardinal Health stated that its "objectives" included "working in partnership" with the chain customers to effect "resolution" of a "suspicious order pattern…prior to supply chain disruption," by taking steps established by the Cardinal Health "Sales" department, such as allowing the "customer/customer store" to set the thresholds and providing "early warning" communications "prior to a SOM event – for example, at 75% of threshold" for "sales to work with the account."[364]

Distributor Defendants including Cardinal Health, McKesson, and AmerisourceBergen all provided early warnings to their chain customers that they were approaching thresholds so that the chains could avoid triggering SOM reporting and adjust ordering patterns by, for example, delaying orders or, more often, obtaining a threshold increase. Cardinal Health provided its early warning reports to its pharmacy distributor customers, including CVS,[365] Walgreens,[366] and Discount Drug Mart.[367] Cardinal Health told NACDS members that they should communicate changes in "purchasing patterns" so Cardinal could "re-evaluate thresholds and change thresholds prior to any supply chain disruption."[368]

Defendants had significant motivation to avoid having customers hit a threshold. DEA had instructed that, if an order "triggered the threshold," then "the entire order" should be "held and not released, "even if part of it came in under the threshold."[369] Thus, orders that hit thresholds would disrupt Defendants' sales and anger their customers. Early warnings at 50-80% of threshold allowed Defendants to either increase the threshold, so it would not be breached, or manipulate ordering patterns to ship the drugs through loopholes that did not trigger SOM.

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[363] Exh. 536, CAH_MDL2804_02366804; Exh. 537, CAH_MDL2804_02366805; Exh. 538, DC00055397; Exh. 539, DC00118615; Exh. 540, CAH_MDL2804_00824833.
[364] Exh. 536, CAH_MDL2804_02366804; Exh. 537, CAH_MDL2804_02366805; Exh. 538, DC00055397; Exh. 539, DC00118615; Exh. 540, CAH_MDL2804_00824833.
[365] Exh. 541, CAH_MDL2804_02299956 at 02299959; Exh. 542, CAH_MDL2804_02185258 at 02185260.
[366] Exh. 543, WAGMDL00119536; Exh. 544, WAGMDL00107485; Exh. 545, WAGMDL00101696.
[367] Exh. 546, DDM00056133.
[368] Exh. 547, CAH_MDL2804_00825380; Exh. 548, CAH_MDL2804_00825381.
[369] Exh. 388, CAH_MDL2804_02489188

The evolution of Cardinal Health's early warning system is telling. Cardinal Health planned to implement a threshold early warning system by at least January 2008, when Cardinal Health internally stated that it was "building in an early warning system" to notify the "sales team" when customers were approaching the SOM threshold so the sales team could "be proactive … evaluate and adjust … before an order that could otherwise be justified is blocked."[370] By February 2008, Cardinal was working with Walgreens to provide an "80% of threshold" advance warning report.[371] On April 4, 2008, Cardinal Health prepared a "SOM Retail Chain" presentation which included an early threshold warning "prior to a SOM event" so "sales" could "work with the account" in order to "eliminate supply chain disruption."[372] Cardinal Health internally discussed that McKesson also engaged in a similar practice, warning customers "at 85% of threshold" and increasing thresholds so that orders would not be held.[373]

In the spring of 2008, Cardinal Health was in the midst of negotiating a settlement of the DEA's regulatory action against it.[374] In April 2008, Cardinal Health asked the DEA if an advance customer threshold notification program was permissible or "contrary to the view that pre-notifying customers of limits could allow illegitimate customers to tailor their orders to avoid detection."[375] Though it does not appear a response from DEA was produced, Cardinal Health documents state it "discuss[ed] the issue[]" with DEA[376] and indicated that the DEA did not grant permission to provide early threshold warnings, as an April 30, 2008 Cardinal document states that "Customers are *not* informed as their purchases approach the monthly threshold."[377] A May 2, 2008 Cardinal Health email

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370 Exh. 549, CAH_MDL_PRIORPROD_DEA07_00884169; Exh. 550, CAH_MDL_PRIORPROD_DEA07_02740938.
371 Exh. 551, CAH_MDL2804_00803437.
372 Exh. 538, DC00055397.
373 Exh. 552, CAH_MDL2804_00834982.
374 Exh. 553, CAH_MDL2804_02508251; Exh. 554, CAH_MDL2804_02508252.
375 Exh. 555, CAH_MDL2804_01376456; Exh, 552, CAH_MDL2804_00834982; Exh. 556, DC00164693.
376 Exh. 557, CAH_MDL2804_01458153.
377 Exh. 558, CAH_MDL2804_00293385 (emphasis added).

describes such warnings as a mere "radar detector," noting that only "allowing the customer go over [the threshold] without warning … truly protects the Supply chain and the Public."[378] In May 2008, Cardinal Health assured the DEA that the "75% of …threshold" report is being generated for "*internal* QRA [compliance] use *only*."[379]

Cardinal Health settled with the DEA on September 30, 2008,[380] and, by December 2008, once no longer under intense DEA scrutiny, Cardinal Health implemented an "early dialogue" procedure through which Cardinal Health's sales team provided early threshold warnings to customers.[381] In 2013 both Cardinal Health and AmerisourceBergen acknowledged that the DEA had not approved divulging thresholds or early warnings to customers.[382] Similarly, in 2014 McKesson admitted that sharing threshold information with customers was improper because it could "give a bad actor the information they need to manipulate the system."[383] Indeed, Cardinal Health suggested the HDA refrain from asking the DEA if it was acceptable to divulge thresholds to customers as a negative response could prove problematic.[384]

The Pharmacy Defendants, who were also self-distributing, conspired to utilize these same early warning systems in their own internal SOM systems, noting that by "flagging the stores at 75%" they could "avoid cutting/reducing orders and subsequently not have to report a SOM to the DEA."[385]

1. Cardinal Health/Walgreens

From 2006 to 2012, Walgreens accounted for approximately 21% of Cardinal Health's annual revenue through the purchases made by Walgreens pharmacies.[386]

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[378] Exh. 559, CAH_MDL2804_00834558.
[379] Exh. 560, CAH_MDL2804_02156859.
[380] Exh. 561, CAH_MDL2804_00641449.
[381] Exh. 562, CAH_MDL_PRIORPROD_AG_0001225.
[382] Exh. 563, CAH_MDL2804_02383809.
[383] Exh. 564, CAH_MDL2804_02447459 at CAH_MDL2804_02447461.
[384] Exh. 563, CAH_MDL2804_02383809 at CAH_MDL2804_02383812.
[385] Exh. 565, WAGMDL00667936.
[386] 2009 Cardinal Annual Report, p. 68 found at https://ir.cardinalhealth.com/financial, reporting/annual-reports/default.aspx; 2012 Cardinal Annual Report, p. 30 found at https://ir.cardinalhealth.com/financial, reporting/annual-reports/default.aspx;

Cardinal Health and Walgreens conspired to avoid their duties under the CSA including in the following ways: Cardinal Health turned a deliberate blind eye to Walgreens' orders, claiming to rely on Walgreens' SOM program.[387] Prior to 2012, however, Walgreens had **no** SOM program for orders to outside Distributors, and thus did not monitor its pharmacies' orders to Cardinal, even if Walgreens itself had cut that pharmacy off for self-distribution.[388] Cardinal Health allowed Walgreens access to its thresholds,[389] and provided Walgreens early warnings at 75% of threshold.[390] Cardinal helped Walgreens to time orders to avoid hitting SOMs reporting triggers,[391] and provided Walgreens with advance notice of due diligence site visits to Walgreens stores.[392] When Cardinal Health identified a Walgreens store with suspicious orders, rather than report to the DEA, Cardinal Health would pass the store to the Walgreens corporate office to determine appropriate follow up.[393] Cardinal notified Walgreens when it intended to stop distribution to a Walgreens store, so that Walgreens could secure other vendors to provide product to that store and could instruct the store not to place additional orders with Cardinal that would have to be reported to the DEA.[394]

2. Cardinal Health/CVS

From 2006 to 2014, CVS accounted for approximately 22% of Cardinal Health's annual revenue,[395] and by 2014, CVS accounted for 28% of Cardinal Health's revenue.[396] In 2014, Cardinal and CVS formed Red Oak Sourcing, a 50/50 generics sourcing joint venture, creating the world's

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[387] Exh. 566, CAH_MDL2804_02289063.
[388] Exh. 567, WAGMDL00492562; Edward Bratton Dep. (12/16/18), Dkt. # 1959-10 at 254-255; Natasha Polster Dep. (01/23/19), Dkt. # 1969-10 at 144-145; 249-250.
[389] Exh. 598, WAGMDL00102642.
[390] Exh. 569, CAH_MDL2804_00783520.
[391] Exh. 570, CAH_MDL2804_00783525.
[392] Exh. 571, CAH_MDL2804_00894654.
[393] Exh. 572, CAH_MDL2804_00865998.
[394] Exh. 573, WAGMDL00246239.
[395] 2009 Cardinal Annual Report, p. 68 found at https://ir.cardinalhealth.com/financial, reporting/annual-reports/default.aspx; 2012 Cardinal Annual Report, p. 30 found at https://ir.cardinalhealth.com/financial, reporting/annual-reports/default.aspx; 2014 Cardinal Annual Report, p. 28 found at https://ir.cardinalhealth.com/financial-reporting/annual-reports/default.aspx.
[396] 2014 Cardinal Annual Report, p. 28 found at https://ir.cardinalhealth.com/financial-reporting/annual-reports/default.aspx.

largest generic drug market[397] in a deal that equated to paying Cardinal Health over $20 Billion dollars annually. Currently, CVS Pharmacy, Inc. provides 25% of the revenue to Cardinal Health, over $34 Billion dollars.[398]

Together, both before and after the venture, Cardinal Health and CVS conspired to avoid their duties under the CSA including: Cardinal Health shirked its nondelegable duty and gave its "proxy" to CVS headquarters to perform due diligence investigations of potentially suspicious orders and individual CVS pharmacies that were ordering excessive amounts of prescription opioids.[399] Cardinal Health turned a deliberate blind eye to that fact that CVS's "sophisticated internal" SOM program, on which Cardinal claimed to rely,[400] was really a theft report without any SOM capabilities.[401] Cardinal Health also contracted with CVS to permit it to set its own threshold quantities for controlled substances at "any value CVS deems appropriate."[402] CVS and Cardinal Health agreed not to disrupt CVS business, even if an order was flagged.[403] Cardinal Health ignored that CVS had no policies, procedures, or programs to monitor prescription opioid orders placed by its pharmacies to Cardinal Health or any other outside vendor until at least 2014.[404] Rather than report suspicious CVS orders to the DEA, Cardinal generally alerted CVS and continued to ship.[405] Even when Cardinal Health identified "consistent… growth of controlled substances … across CVS Chain stores," "unusual"

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397 2014 Cardinal Annual Report, p. 2 found at https://ir.cardinalhealth.com/financial-reporting/annual-reports/default.aspx.

398 2018 Cardinal Annual Report, pp. 4 & 27 found at https://ir.cardinalhealth.com/financial-reporting/annual-reports/default.aspx.

399 *See* Exh. 574, CAH_MDL2804_02506726 ("reason [for not doing visits to stores is that] they are different – have their own Loss Prevention system, therefore we partner with them."), CAH_MDL2804_02506726 at CAH_MDL2804_02506728 ("we approach chains differently in that the know your customer piece is a propriety inquiry of their own internal anti diversion initiatives that is collaborative with cardinal health."); Exh. 542, CAH_MDL2804_02185258 at 60 "Cardinal holds the order and requests store information from CVS. If order is approved, then Cardinal removes hold and possibly customizes threshold for store."

400 Exh. 575, CAH_MDL_PRIORPROD_DEA12_00000695.

401 Mark Vernazza Dep. (11/20/2018), Dkt. # 1971-15 at 191:18-21; 167:6-173:24.

402 Exh. 576, CVS-MDLT1-000030817; Exh. 577, CVS-MDLT1-000030892.

403 *See* Donald Steven Morse Dep., (12/13/18), Dkt. # 1968-9 at 116-117 and Dep. Exh. 4 (He [CVS employee] does not expect Cardinal to interrupt service to CVS stores since they have responded in the manner we originally agreed upon when launching the SOM program.")

404 Exh. 578, CVS-MDLT1-000125301.

405 Exh. 579, CAH_MDL2804_00251459.

ordering, and stores with opioid orders that were thousands of percentage points higher than previous months, Cardinal relied on CVS's assessment that there was "no evidence of controlled substance diversion" and continued to "ship controlled substances to these pharmacies."[406] Cardinal Health alerted CVS to states in which the "DEA and states are aggressive" and might scrutinize the significant increases.[407] Even after the DEA's 2012 regulatory action against Cardinal, CVS and Cardinal conspired to avoid reporting suspicious orders through the "Early Dialogue" process, which provided CVS an early warning at 75% of the threshold limit so CVS could request a threshold increase or delay orders to the next cycle.[408] Cardinal Health readily granted threshold increases and overrides for CVS without appropriate due diligence.[409]

In turn, CVS issued internal instructions to not report to the DEA any orders placed to an outside vendor (like Cardinal Health), even "order[s] deviating from the normal size, frequency, and/or buying pattern and deem the order to not be for legitimate purposes…."[410] In addition to shipping to CVS stores, Cardinal Health also distributed directly to CVS warehouses, which in turn distributed directly to CVS stores. The distributions from Cardinal to CVS warehouses, termed "brokerage sales," were not included in Cardinal Health's SOMs process and did not have set thresholds as other sales did.[411] These orders were not monitored despite the fact that through these orders CVS was ordering so much hydrocodone that it was "able to strip hydrocodone inventory from Cardinal."[412]

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406 Exh 580, CAH_MDL2804_02364440; Exh. 581, CAH_MDL2804_00868921; Exh. 12, CAH_MDL2804_00886155; Exh. 582, CAH_MDL2804_02188524.
407 Exh. 581, CAH_MDL2804_00868921.
408 Exh. 541, CAH_MDL2804_02299956.
409 Exh. 583, CAH_MDL_PRIORPROD_DEA12_00011836; Exh. 584,CAH_MDL_PRIORPROD_DEA12_00011853; Exh. 585, CAH_MDL_PRIORPROD_DEA07_00159466, Exh. 586, CAH_MDL_PRIORPROD_DEA12_00004383.
410 Exh. 529, CVS-MDLT1-000078102.
411 Exh. 587, CAH_MDL2804_00670929; Exh. 588, CAH_MDL2804_00825841.
412 Exh. 589, CAH_MDL2804_00881709.

3. AmerisourceBergen/ Walgreens

In 2013, Walgreens and AmerisourceBergen entered an exclusive distribution agreement as part of an aggressive growth strategy to consolidate and integrate the pharmaceutical industry supply chain.[413] By 2014 Walgreens accounted for 28% of AmerisourceBergen's revenue.[414] Through the deal, Walgreens also gained seats on the AmerisourceBergen Board of Directors.[415] By 2016, Walgreens owned more than 10% of AmerisourceBergen's outstanding common stock and was considered a related party under SEC rules.[416] Despite the addition of Walgreens 8,000 retail locations to AmerisourceBergen's distribution network, and a 200% increase in Schedule II controlled substance orders,[417] AmerisourceBergen only added three additional full time employees to its "Diversion Control Program."[418]

When AmerisourceBergen identified Walgreens stores or orders that raised a "concern" with regard to oxycodone,[419] AmerisourceBergen and Walgreens conspired to avoid reporting to the DEA. AmerisourceBergen stated: "I'm trying to think of everything we can do to prevent having a bunch of orders reported to DEA and held."[420] Despite DEA guidance that "a suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping,"[421] AmerisourceBergen and Walgreens decided to have Walgreens "police their own orders and block any order to [AmerisourceBergen ("ABC")] that would

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413 2014 AmerisourceBergen Annual Report, p. 3-5, found at http://investor.amerisourcebergen.com/financial-information/sec-filings; Exh. 590, WAGMDL00655159.
414 2014 AmerisourceBergen Annual Report, p. 5, found at http://investor.amerisourcebergen.com/financial-information/sec-filings.
415 May 15, 2015 Form 8K, found at http://investor.amerisourcebergen.com/financial-information/sec-filings.
416 2016 AmerisourceBergen Annual Report, p. 72, found at http://investor.amerisourcebergen.com/financial-information/sec-filings.
417 Exh. 591, ABDCMDL00278479.
418 Exh. 592, ABDCMDL00306361.
419 Exh. 593, ABDCMDL00280783.
420 Exh. 594, ABDCMDL00280818.
421 Exh. 595, WAGMDL00490963 at WAGMDL00387659; *see also Masters Pharmaceutical, Inc. v. Drug Enforcement Administration,* 861 F.3d 206, 217-218 (D.C. Cir. 2017)("While deleting or editing orders may have limited the amount of oxycodone flowing to Masters' customers, that practice subverted the Reporting Requirement. The law requires registered suppliers like Masters to alert DEA when their retail-pharmacy customers *attempt* to obtain unusual amounts of a controlled substance, because such attempts are powerful evidence that the pharmacies are operating illegally.").

exceed ABC's threshold thus triggering a suspicious order being sent to DEA from ABC."[422] Requests to clear orders or raise thresholds, however, were almost always approved, as evidenced by the 95%+ approval rate for FY 2014 and 2015.[423]

When orders "outside the expected usage" made it to AmerisourceBergen, AmerisourceBergen and Walgreens set up meetings to discuss adjusting thresholds or using "soft blocking."[424] Contrary to DEA guidance[425] and AmerisourceBergen's stated policy,[426] AmerisourceBergen provided Walgreens with the threshold limits set in AmerisourceBergen's order monitoring program,[427] and also provided Walgreens with weekly SOM statistics.[428] AmerisourceBergen generally would not take action on Walgreens orders that exceeded its thresholds without talking to the Walgreens integrity team.[429]

4. McKesson/CVS

CVS was McKesson's largest customer from 2008-2018, accounting for nearly 20% of McKesson's revenues, over $41 billion, in 2018.[430] CVS conspired with McKesson to keep the drugs flowing and avoid reporting to the DEA. McKesson gave CVS early threshold warnings at 60% of their assigned Schedule II thresholds [431] to provide "plenty of notice" before a SOM event would occur,[432] so that "high volume" purchasers of Schedule II subtances could have their thresholds

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[422] Exh. 596, ABDCMDL00277369; *see also* Exh. 597, CAH_MDL2804_02399918 (AmerisourceBergen's in-house counsel, Elizabeth Campbell stated, "I definitely do not want to ask if the DEA wants us to educate our customers on diversion. They - of course - will say yes. I don't want to put any additional, vague requirements on us.").
[423] Exh. 598, WAGMDL00010887.
[424] Exh. 599, ABDCMDL00278992.
[425] Exh. 600, ABDCMDL00285348.
[426] Exh. 675 (Edward Hazewski Dep. (10/25/18) at 121:22 - 122:2).
[427] Exh. 601, ABDCMDL00282490-00282491; Exh. 675 (Hazewski Dep., at 123:17 - 126:19); Exh. 676 (Elizabeth Garcia Dep. (12/14/18) at 280:23 - 282:1).
[428] Examples of Weekly SOM statics sent to Walgreens include: Exh. 602, WAGMDL00053154; Exh. 603, WAGMDL00047401; Exh. 604, WAGMDL00015414; Exh. 605, WAGMDL00300050.
[429] Exh. 676 (E. Garcia Dep. at 299:19 to 303:11).
[430] See Annual Reports found at https://investor.mckesson.com/reports; 2018 McKesson Annual Report, Dear Shareholder Letter and p. 10.
[431] Exh. 606, MCKMDL00000021 at MCKMDL00000028; Exh. 607, MCKMDL00555966.
[432] Exh. 608, MCKMDL00543554; Exh. 609, MCKMDL00543555; Exh. 610, MCKMDL00543557.

increased accordingly.[433] McKesson routinely increased opioid thresholds for CVS without adequate due diligence.[434] McKesson did not require CVS to provide store level data, but essentially allowed CVS to set its own thresholds.[435] In violation of its internal policy (and DEA requirements) not to increase thresholds without a documented reason, McKesson provided automatic increases.[436] McKesson abdicated its due diligence duties to CVS, relying on CVS to investigate its own suspicious orders,[437] and allowing CVS act as its "proxy in regards to regulatory oversight."[438] McKesson also did not require CVS to provide storewide ordering data.[439] McKesson essentially allowed CVS to monitor itself, despite the fact that CVS had no suspicious order monitoring process relating to McKesson until 2014.[440] CVS also internally stated that it would not report to DEA suspicious orders placed to McKesson, even where CVS knew the orders "deviating from the normal size, frequency, and/or buying pattern and [were] deemed to not be for a legitimate purposes or are at risk of being diverted."[441] Even when McKesson identified suspicious activity, it did not stop shipping nor did it make any report to the DEA. In 2012, McKesson identified 93 CVS pharmacies that were of "concern" because of oxycodone ordering patterns, but McKesson kept shipping and did not report to them.[442]

5. McKesson/Rite-Aid

McKesson and Rite-Aid similarly conspired to avoid suspicious order reporting. McKesson provided Rite-Aid with notification of stores hitting McKesson's thresholds and regularly granted

[433] Exh. 607, MCKMDL00555966.
[434] Exh. 611, MCKMDL00632825; MCKMDL00000497; Exh. 612, MCKMDL00627053; Exh. 613, MCKMDL00521372; Donald Walker Dep. (01/10/19), Dkt. # 1971-19 at 197:7 to 198:6; 201:25 to 202:9.
[435] Walker Dep., Dkt. # 1971-19 at 21:22-22:9; 288:6-291:1.
[436] Walker Dep., Dkt. # 1971-19 at 270:12-271:15, 279:4-23; Exh. 614, MCKMDL00555948; Exh. 615, MCKMDL00627150; Exh. 616, MCKMDL00627151 at MCKMDL00627157.
[437] Exh. 677 (Michael Oriente Dep. (07/19/18) at 547:12-550:1); Walker Dep., Dkt # 1971-19 at 201:25-202:9.
[438] Exh. 617, MCKMDL00445881 at MCKMDL00445883; D. Walker Dep., Dkt. # 1971-19 at 219:18-221:19.
[439] Walker Dep., Dkt. # 1971-19 at 21:22-22:9; 288:6-291:1.
[440] Aaron Burtner Dep. (01/17/19), Dkt. # 1959-13 at 284:21-285:20; Exh. 678 (Ronald Link Dep. at 56:1-57:11; 67:1-7); Exh 679, CVS-MDLT1-000100362 (Ex. 113 to Link Dep.).
[441] Exh. 680 (Craig Schiavo Dep. (01/17/19) at 257:18-258:9); Exh 693, CVS-MDLT1-000078060 at 000078068 (Exh. 16 to Shiavo Dep.)
[442] Walker Dep., Dkt. # 1971-19 at 297:4-299:16.

threshold increases without any due diligence.[443] For example, when a McKesson report revealed a number of Rite Aid stores were at 90% of their threshold and about to be flagged, McKesson offered to – and did - increase the thresholds for *all* Rite Aid locations by 50%.[444] McKesson also forwarded daily monitoring reports to Rite Aid so that Rite Aid could "let [McKesson] know" if McKesson "need[ed] to make any adjustments to current thresholds.[445] On one occasion, Rite Aid noted that over 10% of its stores came close to being blocked, and McKesson simply asked Rite Aid what percentage it wanted the thresholds increased to.[446] McKesson also prompted Rite Aid to delay its orders until the next month in order to avoid hitting monthly thresholds when they were getting close.[447] When Rite-Aid requested an opioid threshold increase from McKesson in one of its Ohio stores to meet the demand of a now-convicted pill mill doctor,[448] McKesson realized the doctor was suspicious but increased the order anyway.[449]

Rite-Aid allowed its stores to order from McKesson without any restriction and failed to take those orders into account in Rite-Aid's self-distribution SOM system, negating the effectiveness of Rite-Aids internal controls.[450] Rite-Aid turned a blind eye to whether McKesson was employing effective SOM on those orders.[451]

Rite Aid admits that it *never* identified any suspicious orders before shipment, much less reported any suspicious orders to DEA.[452]

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[443] Exh. 618, MCKMDL00632967; Exh. 619, MCKMDL00632438; Exh. 620, MCKMDL00628212; Exh. 621, MCKMDL00628193; Exh. 622, MCKMDL00628162; Exh. 623, MCKMDL00628208; Exh. 624, MCKMDL00628135; Exh. 625, MCKMDL00632218; Exh. 626, MCKMDL00645704; Exh. 627, MCKMDL00629858.
[444] Exh. 628, MCKMDL00627723; Exh. 627, MCKMDL00629858.
[445] Exh. 629, MCKMDL00646634.
[446] Exh. 629, MCKMDL00646634.
[447] Exh. 629, MCKMDL00646634.
[448] Janet Getzey Hart Dep. (01/30/19), Dkt. # 1962-21 at 186:3-8; Exh. 630, MCKMDL00632923.
[449] *Id.*; Exh. 682 (Sophia Novack Dep. (01/09/19) at 369:18-370:8).
[450] Hart Dep., Dkt. # 1962-21 at 139:7- 141:23.
[451] Hart Dep. Dkt. # 1962-21 at 142:1-19; Exh. 631, Rite_Aid_OMDL_0040184-98 at 40190.
[452] *See* Response to Plaintiffs' First Set of Combined Discovery Requests to National Retail Pharmacy Defendants at Nos. 3 and 4.

6. McKesson/HBC Giant Eagle/Walmart

McKesson provided daily updates to HBC/Giant Eagle[453] and Walmart[454] when they were approaching McKesson's controlled substance ordering thresholds. McKesson employees often follow up these automated messages with emails that sometimes solicited requests to increase the approaching thresholds.[455]

7. Anda/Rite Aid and Walgreens

Though Anda often internally identified orders or stores of concern when pitching clients or deciding whether to continue or expand business with these clients, there is no evidence that Anda ever reported a suspicious order related to any chain customer, including Rite-Aid and Walgreens. Until at least 2017, Anda used a "screen-out" threshold system of monitoring that rejected orders above a threshold and did not track when a customer attempted to order above that threshold.[456] Instead, it would work with customers to increase their thresholds.[457]

Anda communicated with other distributors about SOM processes and compared systems. For example, in 2008, Anda's CEO answered Cardinal's questions about Anda's Schedule II increase

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[453] As discussed in this section. See also: Exh. 632, HBC_MDL00079213, July 22, 2013 Email from Sarah Medina (Business Process Specialist, RNA Support Solutions, McKesson) to several Giant Eagle employees; Exh. 633, HBC_MDL00079214 (native) is attached to email and shows 63 Giant Eagle pharmacies approaching McKesson's controlled-substance threshold limit, with all but four (4) of them for "oxycodone." Similar emails/threshold spreadsheets at: Exh. 634, HBC_MDL00079386 – 87 (July 17, 2013); Exh. 635, HBC_MDL00079491 – 92 (July 18, 2013); Exh. 636, HBC_MDL00136237 – 38 (Giant Eagle recipients addressed as "Team"). Many more examples in production.

[454] Exh. 153, WMT_MDL_000004480, Nov. 3, 2015, "DEA THRESHOLD WARNING REPORT.XLS" (Spreadsheet showing 81 Walmart stores approaching McKesson ordering threshold with 33 stores at 99% or above); Exh. 637, WMT_MDL_000004478, Nov. 3, 2015, Email, From: Brooke Leverett, Divisional Senior Manager Compliance at Walmart, To: Miranda Johnson, Director, Controlled Substances, at Walmart, Subj.: "RE: 405 Report"; Attachment: "CSMP Report: Follow-Up with Account Manager" ("Attached is the McKesson daily report that is sent.")

[455] Exh. 638, MCKMDL00632580, Jan. 28, 2010, From: Sabrina.Cook@McKesson.com to Giant Eagle employees: ("Team, Please see below for stores that have reached above 90% of threshold. Let me know if there is reason for increases."); *Id.* Gregory Carlson (Giant Eagle) replies to Ms. Cook ("Please increase all by 20%. They are all store [sic] with good growth right now."); Ms. Cook forwards Mr. Carlson's reply to Dave Gustin (McKesson) with "Please see attached."

[456] Exh. 683 (Emily Hall Dep. (01/22/19) at 118:1-13; 121:7-16; See Exh. 639, Anda_Opioids_MDL_0000093641 (2015 Buzzeo Audit of Anda).

[457] Exh. 640, Anda_Opioids_MDL_0000079520; Exh. 641, Anda_Opioids_MDL_0000137355; Exh. 642, Anda_Opioids_MDL_0000137328; Exh. 643, Anda_Opioids_MDL_0000090782; Exh. 644, Anda_Opioids_MDL_0000567745; Exh. 645, Anda_Opioids_MDL_0000566449; Exh. 646, Anda_Opioids_MDL_0000419488.

limit process, telling Cardinal exactly how Anda flags suspicious orders.[458] In 2012, Anda obtained a description of McKesson's SOM Program from Rite Aid.[459] An analysis of the program concluded that, under McKesson's program, a new customer could hypothetically start the year with a monthly Schedule II limit of 1000 and by the end of the year have a limit as high as ~86,500.[460] In 2012, Anda and Rite-Aid discussed the metrics McKesson used for "automatically" increasing Oxy limits, noting that McKesson's formula is "flawed" and will result in having "an issue with a store before you actually realize there is an issue." Anda never reported the flaws in McKesson's SOM program to the DEA.[461]

8. H.D. Smith

When H.D. Smith discovered a suspicious customer, exclaiming internally "[t]hat's a lot of pills!,"[462] it questioned whether to report them to the DEA, noting that it did not "want to draw unnecessary scrutiny from a regulatory agency."[463] Even when an order was identified as suspicious, H.D. Smith instructed internally "[i]n most cases the customer will not be reported to DEA as suspicious," but rather thresholds would be increased "plus a buffer to account for some increased sales."[464] H.D. Smith was "open with … customers," sharing thresholds and other SOM related information.[465] [redacted]

[458] Exh. 647, Anda_Opioids_MDL_0000616647.
[459] Exh. 648, Anda_Opioids_MDL_0000085935.
[460] Exh. 649, Anda_Opioids_MDL_0000085936.
[461] Exh. 650, Anda_Opioids_MDL_0000726927.
[462] Exh. 651, HDS_MDL_00318081.
[463] Exh. 652, HDS_MDL_00136562.
[464] Exh. 653, HDS_MDL_00178074.
[465] Exh. 653, HDS_MDL_00178074.
[466] Exh. 654, HDS_MDL_00218623.

9. Mallinckrodt / Walgreens

In 2013, Walgreens received an administrative warrant and subpoenas and believed its Perrysburg Ohio distribution center was about to be shut down by the DEA.[467] Within days of receiving the warrants and subpoenas, Mallinckrodt began to work with Walgreens to "put all hands on deck" to immediately reroute Walgreens's opioid supply through other distributors, including Cardinal Health and Anda, so that the pills would keep flowing.[468]

SUMMARY JUDGMENT STANDARD

The moving party has the burden of showing that no genuine dispute of material fact exists. *Hickle v. Am. Multi-Cinema, Inc.*, 927 F.3d 945, 951 (6th Cir. 2019). Summary judgment must be denied "if a reasonable jury could return a verdict for the nonmoving party[.]" *Kolesar v. Allstate Ins. Co.*, No. 1:19 CV 35, 2019 WL 2996047, at *2 (N.D. Ohio July 9, 2019) (Polster, J.) (citing *Baynes v. Cleland*, 799 F.3d 600, 606 (6th Cir. 2015)). In making this determination, "the court must view the facts and any inferences reasonably drawn from them in the light most favorable to the nonmoving party." *Id.* (citing same). Courts do not weigh the evidence or otherwise engage in "jury functions" in deciding a motion for summary judgment; "[i]f there remains any material factual disagreement as to a particular legal claim, that claim must be submitted to a jury." *Hickle*, 927 F.3d at 951 (citing *Bobo v. United Parcel Serv., Inc.*, 665 F.3d 741, 748 (6th Cir. 2012)).

RICO / OCPA ARGUMENT

RICO requires a plaintiff to demonstrate: (1) the existence of an enterprise; (2) control or participation in the enterprise's conduct; (3) through a pattern; (4) of racketeering activity (the "predicate acts"); (5) causation; and (6) injury to business or property. 18 U.S.C. § 1962(c); *see also In re ClassicStar Mare Lease Litig.*, 727 F.3d 473, 483 (6th Cir. 2013).[469] Put simply, a plaintiff may prove a

[467] Exh. 655, WAGMDL00493697; Exh. 656, WAGMDL00493694; Exh. 657, WAGMDL00493701; Exh. 658, WAGMDL00493704; Exh. 569, WAGMDL00493707; Exh. 660, WAGMDL00493710; Exh. 661, WAGMDL00493713; Exh. 662, WAGMDL00493716; Exh. 663, MNK-T1_0005639179.
[468] Exh. 663, MNK-T1_0005639179.
[469] Because the OCPA is patterned after the federal RICO statutes, the elements are the same. *Robins v. Global Fitness Holdings, LLC*, 838 F. Supp. 2d 631, 651 (N.D. Ohio 2012) (Polster, J.) (citing cases).

RICO violation by showing that a group of persons or entities came together with a common goal, and achieved that common goal by engaging in a pattern of racketeering activity. The RICO Defendants do not challenge the pattern or predicate act elements; they seek summary judgment on their claims that Plaintiffs fail to offer evidence on four elements: enterprise, control or participation, causation, and damages.

I. THERE IS A GENUINE DISPUTE OF MATERIAL FACT REGARDING THE EXISTENCE OF THE OPIOID MARKETING AND SUPPLY CHAIN ENTERPRISES

The Supreme Court has recognized that the concept of an "enterprise" is "obviously broad," encompassing "*any* . . . group of individuals associated in fact." *Boyle v. U.S.*, 556 U.S. 938, 944 (2009) (the "very concept of an association in fact [enterprise] is expansive."). The only necessary structural features of an association-in-fact enterprise are: "a purpose, relationships among those associated with the enterprise, and longevity sufficient to permit these associates to pursue the enterprise's purpose." *Id.* at 946; *In re ClassicStar Mare Lease Litig.,* 727 F.3d at 492-93 (challenging the existence of an enterprise cannot be done easily "given the Supreme Court's repeated admonitions that the term 'enterprise,' like the RICO statute itself, should be interpreted broadly"); *Ouwinga v. Benistar*, 694 F.3d 783, 794 (6th Cir. 2012) ("Put another way, a plaintiff must show 'simply a continuing unit that functions with a common purpose.'"); *Robins v. Global Fitness Holdings, LLC*, 838 F. Supp. 2d 631, 651 (N.D. Ohio 2012); *see also In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2018 WL 4895856 at *17 (N.D. Ohio Oct. 5, 2018) (an association-in-fact enterprise "need not have a hierarchical structure or chain of command, decisions may be made on an ad hoc basis and by any number of methods … Members of the group need not have fixed roles; different members may perform different roles at different times.") (quoting *Boyle*, 566 U.S. at 944, 948).

Section 1962(c) allows an injured plaintiff to impose RICO liability broadly on any "person" who "conduct[s] or participate[s], directly or indirectly, in the conduct of such enterprise's affairs." 18 U.S.C. § 1962(c). The word "conduct" "requires an element of direction," but the word "participate"

is a "term of breadth." *Reves v. Ernst & Young*, 507 U.S. 170, 178 (1993); *id.* at 179 (""To participate … in the conduct of affairs' must be broader than 'to conduct.'"). "Of course, the word 'participate' makes clear that RICO liability is not limited to those with primary responsibility for the enterprise's affairs, just as the phrase 'directly or indirectly' makes clear that RICO liability is not limited to those with a formal position in the enterprise, but some part in directing the enterprise's affairs is required." *Id.* To have "some part in directing the enterprise's affairs," *id.*, a defendant need only "mak[e] decisions on behalf of the enterprise or . . . knowingly carry[] them out." *U.S. v. Fowler*, 535 F.3d 408, 418 (6th Cir. 2008) (citation omitted). An enterprise can be operated by "lower rung participants in the enterprise." *Id.* at 419.

The defendant whose conviction was affirmed by the Supreme Court in *Boyle* was not a control person or "core" participant. 556 U.S. at 941. Neither was the group *Boyle* held to constitute a RICO enterprise structured in any formal or express way. "It does not appear to have had a leader or hierarchy; nor does it appear that the participants ever formulated any long-term master plan or agreement." *Id.* An enterprise can be proved by the deeds of its participants; no evidence of any express agreement is required. *Id.* at 941. As held in *Turkette* and *Boyle*, the existence of an enterprise may properly be inferred from the evidence showing that the persons alleged to have participated in an enterprise engaged in a pattern of racketeering activity. *Id.* at 947. In short, the evidence used to prove the pattern of racketeering activity and the evidence establishing an enterprise "may in particular cases coalesce." *Id.*, quoting *Turkette*, 452 U.S. 576, 583 (1981). *See also Ouwinga*, 694 F.3d at 794 (6th Cir. 2012) (""[A] pattern of racketeering activity may be sufficient in a particular case to permit a jury to infer the existence of an association-in-fact [enterprise].'") (quoting *Boyle*, 556 U.S. at 951); *Wyndham Vacation Resorts, Inc. v. VP Transfers, LLC*, 3:12-CV-1327, 2013 WL 4510954, at *7 (M.D. Tenn. Aug.

27, 2013) ("The existence of an enterprise may be inferred from evidence of the illegal conduct committed by members of the enterprise.").[470]

Here, Plaintiffs have demonstrated an extensive pattern of racketeering activity through violations of the CSA—which the RICO Defendants do not here dispute—and from which this Court may infer a RICO enterprise. *Boyle*, 556 U.S. at 947; *Turkette*, 452 U.S. at 583. In addition, as explained below, the summary judgment record contains direct evidence that supports the existence of two RICO enterprises. At a minimum, that evidence raises a genuine issue of material fact as to the existence of a RICO enterprise such that summary judgment is not appropriate. *See Negrete v. Allianz Life Ins. Co. of N. Am.*, CV 05-6838 CAS MANX, 2011 WL 4852314, at *7-8 (C.D. Cal. Oct. 13, 2011) (rejecting defendant's argument that competitors cannot share a common purpose, and therefore denying defendant's summary judgment motion).

A. The Summary Judgment Record Establishes a Genuine Issue of Material Fact Regarding the Opioid Marketing Enterprise

Manufacturers contend that plaintiffs cannot prove the existence of an Opioid Marketing Enterprise because: (1) there is no evidence of coordination among the RICO Manufacturer Defendants for an unlawful purpose and (2) there is no evidence that the RICO Manufacturer Defendants controlled or directed the activities of their front groups and KOLs. As discussed below, however, the summary judgment record provides ample evidence to support the existence of an Opioid Marketing Enterprise.

[470] *See Almanza v. United Airlines, Inc.*, 851 F.3d 1060, 1069 n.6 (11th Cir. 2017) ("[T]he *Twombly* parallel-conduct pleading standard, which was developed for the 'agreement' element of a Sherman Act § 1 conspiracy claim, applies equally to both RICO enterprise and RICO conspiracy allegations."); *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1294–95 & n.5 (11th Cir. 2010) (RICO case; noting that the *Twombly* court "acknowledged that certain examples of a parallel conduct might be sufficient to imply a conspiracy, such as 'parallel behavior that would probably not result from chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties[,]'" but finding that "[t]he conduct alleged here does not fall into any of these categories") (quoting *Twombly*, 550 U.S. at 557 n.4).

1. The Record Confirms that the RICO Manufacturer Defendants Formed Relationships to Advance Their Common Goal of Expanding the Opioid Market

The RICO Manufacturer Defendants argue (Dkt. # 1930 at 15-17) that there is no evidence that they: (1) coordinated rather than acted independently or (2) coordinated for an unlawful purpose. They contend (Dkt. # 1930 at 16) that their memberships in trade associations, such as the PCF, cannot be used as evidence of coordination to prove a RICO enterprise. These arguments lack merit.

As explained below, the record demonstrates that the RICO Manufacturer Defendants coordinated their conduct in furtherance of a common purpose—to dramatically expand the opioid market—using relationships they developed through direct interactions, through their memberships in the PCF, and through their coordinated use of front groups and KOLs to promote their unified message. Their marketing conduct was anything but independent, parallel action.

The RICO Manufacturer Defendants began working together on their plan to expand the market for prescription opioids by coordinating as early as 2000, referring to their coordinated efforts as a "pain franchise" and seeking to "protect the pain movement." *See supra*, pp. 8-9. The RICO Manufacturer Defendants' common goal was to expand the opioid market through several common and coordinated strategies: the use of front groups and KOLs to promote opioids as a safe and effective pain treatment; the use of patient advocacy groups to promote the need to treat pain; and altering the standards governing physicians to remove fear of disciplinary action for prescribing opioids. *See supra*, pp. 10-27.

Because the unified messages that the RICO Manufacturer Defendants sought to promote through those marketing efforts were not supported by scientific or clinical evidence, they could not themselves promote those messages without running afoul of the FDA. *See supra*, pp. 7 & n.24, 9 & n.35. Moreover, Defendants recognized that it was going to take a "real team effort" to "protect the pain movement;" advocacy by any one Defendant would not be successful in changing the medical consensus governing the use of opioids. *See supra*, pp. 9-11. As they were advised by one of their

trusted KOLs, Dr. Kathleen Foley, they "need[ed] to speak with ONE VOICE" to effectively promote the use of opioids. *See supra*, p. 10. As she explained to Purdue:

> I think that there is a tightrope that you need to walk, because you are a drug company and it would be much better if the advocacy came from outside the drug company and even better without much in the way of support from you. So along those lines, the kind of things that I am thinking of is that maybe we should call a meeting, bring together representatives from all of the companies, ideally high level representatives, like presidents or major leaders and strategize about the way to play the media issues.[471]

It is no coincidence that, in the wake of that advice, the RICO Manufacturer Defendants communicated with each other about the pain movement to assure coordinated and consistent advertising and public relations. For example, Cephalon and Purdue met "to build a formal or informal coalition on" pain issues; Purdue and Janssen agreed not to use reports of opioid abuse in promoting OxyContin; Janssen communicated to another KOL, Dr. Portenoy, that it had "called others [about news reports of abuse of Purdue's OxyContin] to try help . . . protect the pain movement," Cephalon, Janssen, and Purdue met, and notes from that meeting reflect a discussion of "collab—need to coalesce a key msg," and "how to exploit decade of pain;" and Johnson & Johnson (Janssen) shared an article with Cephalon, Purdue, and others, about patients' need for opioids to treat pain, stating that "this is what **we** have always said." *See supra*, pp. 8-11.

The evidence further shows that RICO Manufacturer Defendants all maintained relationships with the same, discrete group of front groups and KOLs. *See supra*, pp. 11-22. Those front groups and KOLs had impartiality and scientific credibility that, as Dr. Foley pointed out, the RICO Manufacturer Defendants lacked because of their inherent commercial interests. *See supra*, pp. 10-12. The RICO Manufacturer Defendants' relationships with the front groups and KOLs are demonstrated both through their substantial funding of those groups and KOLs, and by the fact that many of their high-ranking employees assumed key leadership positions in those front groups. *See supra*, pp. 12-21. Moreover, the articles and materials produced by each of these front groups and KOLs promoted the

[471] Exh. 41, PPLPC037000008901.

same false messages about the safety and effectiveness of opioids that the RICO Manufacturer Defendants had urged. *See supra*, pp. 11-22. In addition, all of the RICO Manufacturer Defendants belonged to the Pain Care Forum, the very purpose of which was to "fill the vacuum of leadership in the community at large, and provide for some **unified direction** on issues of importance to the pain community." *See supra*, pp. 21-22.

From all of this evidence, a jury could reasonably conclude that the RICO Manufacturer Defendants agreed to implement Dr. Foley's strategy and consciously and cooperatively engaged in a joint marketing scheme, using third parties or fronts, to promote the widespread use of opioids in order to expand the market. The extensive web of relationships and communications among the various RICO Manufacturer Defendants and these third-party groups and KOLs in furtherance of the common marketing purpose supports the existence of an agreement.

Indeed, the volume of communications between and among the RICO Manufacturer Defendants and those third-parties, the overlap between the front groups and KOLs used by the individual RICO Manufacturer Defendants, and the uniformity of the message promoted by these Defendants, the third parties, and the KOLs, render completely implausible the suggestion that the RICO Manufacturer Defendants' conduct was wholly independent. The RICO Manufacturer Defendants' reference (Dkt. # 1930 at 16) to one witness claiming that he does not recall any coordination with one particular manufacturer, Endo, is insufficient, in light of the evidence discussed above, to conclude that there is no genuine factual dispute as to the existence of a RICO Marketing Enterprise.

The RICO Manufacturer Defendants cite (Dkt. # 1930 at 16) *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1295 (11th Cir. 2010), for the proposition that participation in a trade organization does not support a RICO violation and, consequently, that their mere membership in the PCF does

not prove they formed an enterprise.[472] Plaintiffs' argument is not that membership or participation in a trade organization itself proves a RICO violation. Rather, the PCF is merely one forum where direct coordination occurred among the RICO Manufacturer Defendants to promote their expansion of the opioid market. *Am. Dental*—a RICO conspiracy case that does not address any of the structural or substantive issues required for proving the existence of a RICO enterprise—does not preclude consideration of trade association conduct. *Id.* at 1291-93.

The RICO Manufacturer Defendants cite (Dkt. # 1930 at 17) to *Almanza v. United Airlines*, 851 F.3d 1060, 1068 (11th Cir. 2017), and *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 374 (3d Cir. 2010), for the proposition that competitors independently engaging in similar transactions with similar firms does not prove a common purpose. But here, unlike in those cases, Plaintiffs have not rested on barebones or "conclusory" allegations of concerted action.

Defendants also suggest (Dkt. # 1930 at 5) that Plaintiffs must show that the asserted common goal is "to achieve an unlawful common purpose," and that seeking to expand the opioid market is not unlawful. But an unlawful common purpose is **not** required for a RICO violation. Rather, RICO requires a common purpose that a defendant carries out through unlawful conduct. *See, e.g., Boyle*, 556 U.S. at 944-45; *Robins*, 838 F. Supp. 2d at 653. Thus, even if the common purpose of the Opioid Marketing Enterprise, to expand the opioid market, is itself legal (a highly dubious proposition given the CSA strictures), Defendants are not relieved from RICO liability if they engaged in unlawful conduct to achieve that end. Tellingly, Defendants here do *not* challenge the existence of unlawful conduct (*i.e.*, predicate acts).[473]

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[472] Here, again, Manufacturers confuse the existence of an association-in-fact enterprise, with evidence of a RICO violation.

[473] To the extent the Manufacturer Defendants suggest that their marketing was lawful because they lacked knowledge that any of their statement regarding opioids were false or misleading, such an assertion strains credulity. *See, e.g.,* United States Government Accountability Office Report to Congressional Requesters, *Prescription Drugs; OxyContin Abuse and Diversion and Efforts to Address the Problem* (December 2003) (noting Perdue had been cited twice by the FDA for illegal marketing activities, and that the FDA had also sent enforcement letters to other opioid manufacturers for marketing and promotion violations); Richard Fanelli Dep. (12/07/18), Dkt. # 1961-26 at 353 (admitting that the "entire industry" was aware of the

In any event, the common purpose was not simply to market prescription opioid for their intended uses. If that were the goal, then members of the Opioid Marketing Enterprise would not have dubbed themselves the "Pain Mafia"[474] and worked together to identify strategies to "protect the pain movement." *See supra*, pp. 8, 9. Rather, as described above, the common purpose of the Opioid Marketing Enterprise was to expand the market for prescription opioids by engaging in fraudulent marketing representations (*i.e.*, unlawful conduct), including through the use of front groups and KOLs because these: (a) had an appearance of impartiality or credibility that the drug companies lacked; and (b) were not subject to FDA regulation. Indeed, Defendants knew that the marketing message they sought to promote was unlawful, because they promoted the use of prescription opioids for off-label uses and without disclosing significant health risks, despite warnings from the FDA about such unlawful marketing. Among ostensible competitors, necessity is the mother of agreement. That the RICO Manufacturer Defendants, individually, might not have been able to influence or direct the front groups or KOLs to promote their desired message, is yet another factor that supports an inference of an agreement among the RICO Manufacturer Defendants.

2. Plaintiffs Do Not Need To Prove That the RICO Manufacturer Defendants Controlled or Directed their Front Groups and KOLs

The RICO Manufacturer Defendants assert (Dkt. # 1930 at 17-19) that there is no evidence showing their control or direction of the front groups and KOLs. But Plaintiffs do not need to show this. As explained above, the record reveals that the RICO Manufacturer Defendants combined to form a Marketing Enterprise to expand the opioid market through fraudulent messages. Section 1962(c) of RICO permits recovery against any "person" who "conduct[s] or participate[s], directly or indirectly, in the conduct of such enterprise's affairs." 18 U.S.C. § 1962(c). Thus, Plaintiffs must show

GAO's 2003 report). They were also aware that there was no scientific evidence to support their broad messages about the safety and efficacy of opioids. Report of Anna Lembke, MD, Dkt. # 2000-10, at 5, 21-75, Appendix I.A, I.B, I.C, I.D, and I.E.; Report of David Kessler, MD, Dkt. # 2000-8, at 40-46, 56-61, 62-73, 94-100 134-39, 140-47, 173-80, 193-200, 254-58, 275-76, 285-89; Report of David S. Egilman, MD, MPH, Dkt. # 2000-5, at 62, 70.

[474] *See* Exh. 665, AAPA_00026010.

that the participants in the Marketing Enterprise—the RICO Manufacturer Defendants—took "some part in directing the enterprise's affairs," *Reves*, 507 U.S. at 179, or made "decisions on behalf of the enterprise or . . . knowingly carr[ied] them out," *Fowler*, 535 F.3d at 418. The record plainly shows that the RICO Manufacturer Defendants were actively involved in orchestrating and perpetrating their marketing scheme, which included the use of front groups and KOLs. *See supra*, pp. 11-22.

Plaintiffs do not seek to impose RICO liability on the front groups or KOLs, however, and Plaintiffs do not argue that they are participants in the RICO Marketing Enterprise.[475] Accordingly, there is no reason that Plaintiffs need to prove that the RICO Manufacturer Defendants controlled or directed the front groups or KOLs. Defendants provide no authority to the contrary. The RICO Distributors further argue (Dkt. # 1904 at 6-7) that they did not join the Opioid Marketing Enterprise. Plaintiffs do not argue that they did.

B. The Summary Judgment Record Establishes a Genuine Issue of Material Fact Regarding the Opioid Supply Chain Enterprise

The RICO Supply Chain Defendants move for summary judgment on the ground that there is no evidence that they formed an illicit enterprise, arguing that there is no evidence of an "ongoing organization"[476] for an "unlawful common purpose." *See* Dkt. # 1904 at 3. Distributors also contend (Dkt. # 1904 at 2) that there is no evidence that "a Distributor directed the affairs of any such enterprise" (Dkt. # 1904 at 2)[477] and that Plaintiffs improperly rely on certain types of evidence to establish a RICO violation. *See* Dkt. # 1904 at 4-10. They are incorrect. As explained below, the record demonstrates that the RICO Supply Chain Defendants coordinated with each other to form the Opioid Supply Chain Enterprise to protect the supply chain (*i.e.,* to make sure all orders became completed sales and reached the ultimate customer) to maximize their profits.

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[475] Defendants apparently misunderstood that Plaintiffs sought to prove at trial a broader Marketing Enterprise that included the front groups and KOLs. *See, e.g.,* Dkt. # 1904 at 17-19. That is not the case.

[476] Manufacturers' minimal arguments on the Opioid Supply Chain Enterprise similarly challenge that they were coordinating while repeating their arguments about trade associations that are addressed above. Dkt. # 1930 at 19-20.

[477] Defendants' arguments as to each of these alleged evidentiary insufficiencies are cursory and not properly supported by argument. For that reason alone, this Court should deny summary judgment on any of those grounds.

1. The Record Confirms that the RICO Supply Chain Defendants Joined Together to Advance Their Common Goal of Protecting the Opioid Supply Chain.

The Distributor Defendants began working together on issues related to protection of the supply chain and maximizing their profits since at least 1996. *See supra*, p. 28. When Purdue released OxyContin in 1996, the RICO Supply Chain Defendants began meeting together to discuss ways to mutually support each other (*i.e.* direct relationships). *See supra*, p. 28. As time moved on, the direct meetings and coordination were supplemented by the creation of numerous trade and working groups, such as the PCF and HDA, which facilitated coordination among the Defendants for the common purpose of protecting the Opioid Supply Chain. *See supra*, pp. 31-38, 42-59. Especially after the start of the Distributor Initiative, the RICO Supply Chain Defendants used their direct relationships and membership in groups like the HDA to coordinate their activities in relation to diversion and suspicious order monitoring, lobbying in support of legislation that would better enable defendants to protect the supply chain without adverse legal ramifications, and to support information sharing and coordination within the supply chain industry on compliance and other matters. *See supra*, pp. 30-51. The RICO Supply Chain Defendants discussed, shared, and assisted one another on all issues related to suspicious order monitoring. *See supra*, pp. 38-46.

The RICO Supply Chain Defendants observed that they were "all in the same boat" and that collaboration was necessary to ensure the benefit and protection of all members of the enterprise. *See supra*, pp. 30 n. 156, 32-36. As the RICO Supply Chain Defendants explained, "remain[ing] in close contact with each other whenever there may be a questionable order" was necessary to "protect ourselves and our registrations regarding suspicious order discovery and reporting." *See supra*, p. 32. The RICO Supply Chain Defendants worked together to "gang up on the DEA," while simultaneously holding meetings for the purpose of coordinating responses to diversion, suspicious patterns, and ensuring that there was "no interrupting in the supply chain." *See supra*, pp. 34, 38-42. These meetings were designed to bring the industry together and the purpose was clear: "maximize [their] shared

objectives," while "collaborating . . . and supporting [each other] on matters of mutual interest." *See supra*, pp. 33-36. Defendants directly discussed and interacted with each other concerning their approach to suspicious order monitoring, reporting, and shipping requirements, including sharing of information that the RICO Supply Chainr Defendants were not reporting suspicious orders. *See supra*, pp. 36-42.

Indeed, in 2007 and 2008, the RICO Supply Chain Defendants, who were all members of the HDA, coordinated with each other through that setting, to advance their mutual goal of protecting the supply chain. *See supra*, pp. 42-57. They used their membership in that organization as a platform to convince the DEA that they were working together to develop industry guidelines that would improve the industry's compliance with the CSA and its implementing regulations. *See supra*, pp. 44-46. But the ICGs were, in fact, a ruse. *See supra*, p. 46. The RICO Supply Chain Defendants knew that they had no intention to implement or comply with the ICGs, but that they were merely intended to divert attention from their regulatory non-compliance, and therefore advance the Defendants' common goal. *See supra*, pp. 45-47. Defendants also coordinated through their HDA membership and the PCF to support the Marino Bill, which further protected the supply chain by limiting the DEA's enforcement authority. *See supra*, pp. 47-51.

The foregoing record provides the Court with over twenty years of coordinated efforts that furthered the purpose of the Opioid Supply Chain Enterprise, through a variety of forums, including direct interaction and coordination through the HDA and the PCF, and direct partnering between the RICO Supply Chain Defendants. From this evidence of same or similar conduct regarding suspicious orders and suspicious order monitoring (including not reporting suspicious orders), constant communication and coordination between defendants, both directly and through trade and working groups (including sharing suspicious order monitoring policies), a jury could reasonably infer that the RICO Supply Chain Defendants' actions were more than just independent, parallel conduct, but

instead are consistent with the existence of an Opioid Supply Chain Enterprise to protect the supply chain and the resulting profits.

The RICO Distributor Defendants argue (Dkt. # 1904 at 2-3) that there is no evidence of a common unlawful purpose. As explained above, however, plaintiffs need only prove "a common purpose of engaging in a course of conduct." *Boyle*, 556 U.S. at 944; *see also Robins*, 838 F. Supp. 2d at 651 ("a common purpose of engaging in unlawful conduct"). The record amply demonstrates that common purpose. The RICO Supply Chain Defendants coordinated to protect the opioid supply chain to ensure that sales were completed and profits were maximized. *See supra*, pp. 27-28, 31-38. They did so by sharing and coordinating their suspicious order monitoring programs, including information about how to evade DEA enforcement, skirt compliance rules, or cheat the system. *See supra*, pp. 38-42. And there were voluminous communications. *See supra*, pp. 27-42. From all of the evidence, a jury could reasonably conclude that the RICO Supply Chain Defendants agreed on measures to protect the supply chain, including by evading compliance with the CSA.

The RICO Defendants further contend (Dkt. # 1930 at 19; Dkt. # 1904 at 3-4) that membership in the HDA does not show participation in an enterprise. This argument should be rejected for the same reasons as the RICO Manufacturer Defendants' argument concerning membership in the PCF. *See supra*, p. 80.

2. Record Evidence Confirms the RICO Distributor Defendants' Control and Participation in the Affairs of the Opioid Supply Chain Enterprise

The RICO Distributor Defendants cursorily argue (Dkt. # 1904 at 2) that there is no evidence "that a Distributor directed the affairs of any" Supply Chain Enterprise. RICO's control or participation element requires a plaintiff to show only that the defendant had "some part" in directing the affairs of the enterprise by "making decisions on behalf of the enterprise or . . . knowingly carrying them out." *Reves*, 507 U.S. at 178-79; *Fowler*, 535 F.3d at 419. That element is easily satisfied here. As explained above, the RICO Distributor Defendants repeatedly made decisions on behalf of the Supply

Chain Enterprise to support the common goal of protecting the supply chain, such as coordinating with the RICO Manufacturer Defendants about suspicious orders and suspicious order monitoring, refusing to stop suspicious orders, and by helping pharmacies to evade thresholds that otherwise would have required an order not to be shipped. *See supra*, pp. 36-42, 59-73. There is also evidence that the RICO Distributors carried out decisions on behalf of the Supply Chain Enterprise, such as working through the HDA and PCF to help develop the ICGs, and by not disclosing other distributors' failure to report suspicious orders. *See supra*, pp. 37-42, 44-46.

3. The RICO Distributor Defendants' Argument That This Court Should Ignore Evidence of Certain Types of Conduct is Baseless

The RICO Distributor Defendants identify categories of conduct which they assert cannot support liability for a RICO claim. *See* Dkt. # 1904 at 4. As discussed below, however, such conduct supports the existence of the Opioid Supply Chain Enterprise.

a. Lobbying

The RICO Distributor Defendants argue (Dkt. # 1904 at 4) that the *Noerr-Pennington* doctrine immunizes them from liability for lobbying, which is protected First Amendment activity. But Plaintiffs do not attempt to impose liability upon the RICO Supply Chain Defendants for their lobbying activities, or argue that the lobbying was unlawful conduct. The basis for liability (*i.e.* the pattern of racketeering activity) for the RICO Supply Chain Enterprise is repeated violations of the CSA, in particular the no-shipping duty. Plaintiffs do not argue that lobbying is a predicate act.

Rather, as described above, *see supra*, pp. 47-50, the RICO Supply Chain Defendants' lobbying in support of the Marino Bill provides evidence of the common purpose of the Opioid Supply Chain Enterprise, as well as evidence of relationships and coordinated behavior to prove the existence of the enterprise. While this conduct does not directly create liability as a pattern of racketeering activity, it

supports the conclusion that the enterprise was conducting ongoing activities and functioned as a continuing unit.[478]

b. Production Quotas

The RICO Distributor Defendants argue (Dkt. # 1904 at 5) that there is no evidence of an agreement to influence quotas and that, even if there were, they are shielded from liability under the *Noerr-Pennington* doctrine. Here, again, the RICO Distributor Defendants misunderstand the law and Plaintiffs' claims. The pattern of racketeering activity to support the RICO Supply Chain Enterprise claim is based on violations of the CSA through repeated refusals to identify, report, and halt suspicious orders. Influencing production quotas is not the alleged unlawful conduct, nor even the alleged common purpose of the Supply Chain Enterprise. *Noerr-Pennington*, therefore, is not implicated.

c. Suspicious Order Reporting

The RICO Distributor Defendants argue (Dkt. # 1904 at 5) that there is no evidence of an agreement through the HDA to not report suspicious orders. Alternatively, they argue that any evidence of failure to report suspicious orders was the result of lawful, independent conduct. They are incorrect either way.

First, there is ample evidence, described above, from which a jury could reasonably conclude that the RICO Supply Chain Defendants formed agreements about their approach to suspicious order monitoring through multiple avenues, including: direct interactions that indicated Distributors and

[478] Evidence of Defendants' petitioning conduct is relevant and admissible to show the purpose and character of Defendants' wrongful activities. *See United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 n.3 (1965) ("It would of course still be within the province of the trial judge to admit this evidence, if he deemed it probative and not unduly prejudicial, under the 'established judicial rule of evidence that testimony of prior or subsequent transactions, which for some reason are barred from forming the basis for a suit, may nevertheless be introduced if it tends reasonably to show the purpose and character of the particular transactions under scrutiny."); *see also, e.g., In re Welding Fume Products Liab. Litig.*, 1:03-CV-17000, 2010 WL 7699456, at *93 (N.D. Ohio June 4, 2010) (noting that it previously declined to issue a pretrial, blanket ruling excluding all evidence of the defendants' lobbying activities, and in fact had "admitted several such documents over defendants' objection because, even though the document was arguably created for lobbying purposes, it also contain[ed] statements directly relevant to issues central to every *Welding Fume* case"). Here, the evidence demonstrates Defendants' knowledge and intent to participate in a RICO enterprise and in the conspiracy to increase sales by refusing to report or halt suspicious orders.

Manufacturers had agreed to mutually support each other in not reporting suspicious orders, and through their work in groups like the HDA and PCF. *See supra*, pp. 37-42, 44-46. Each member of the Opioid Supply Chain Enterprise failed to report suspicious orders in similar ways. *See supra*, pp. 37-42. This is enough evidence—especially considering the additional evidence that much of RICO Defendants' communications concerning suspicious order monitoring were admittedly conducted verbally—from which a jury could reasonably infer that there was at least a tacit agreement.[479]

Second, the RICO Distributor Defendants' argument that parallel conduct cannot prove an enterprise is incorrect. Plaintiffs may prove their enterprise allegations through a setting which provides context to understand that allegedly parallel conduct is, in fact, coordinated action.[480] The cases relied on by Distributors, in fact, support this point.[481] But Plaintiffs' case is not based on mere parallel conduct.

Here, as the Court previously recognized, Plaintiffs' claims are premised on the fact that "the PCF and HDA created a private network where representatives of the Manufacturers and Distributors could form relationships and create alliances and hold strategic discussions between high-level executives."[482] The prime example of these discussions between high-level executives occurred directly between the RICO Supply Chain Defendants when they discussed their approach to suspicious order monitoring, the DEA regulations concerning the same, and the creation of policies and procedures for suspicious order monitoring. *See supra*, pp. 38-42. Another example of coordination through the HDA is the creation of the ICGs. *See supra*, pp. 44-47. Based on these facts, Plaintiffs' evidence satisfies *Boyle*, and distinguishes Distributors' cases.

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[479] Exh. 666, PPLP004469431 [Purdue's Jack Crowley explaining to Donald Walker, in communicating about suspicious orders, that "Most of the time we do a lot of this communication verbally."].
[480] *Atlantic v. Twombly*, 550 U.S. 544, 557 (2007).
[481] *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1295 (11th Cir. 2010) ("The Court stated in *Twombly* that 'when allegations of parallel conduct are set out . . . they must be placed into a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action.'"); *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 374 (3rd Cir. 2010).
[482] *See In re Nat'l Prescription Opiate Litig.,* Case No. 18-op-45090, 2018 WL 4895856, at *5 (N.D. Ohio Oct. 5, 2018).

d. Expanding the Market

The RICO Distributor Defendants assert (Dkt. # 1904 at 10) that there was no ongoing organization whose common purpose was to expand the market but that, if there were, such purpose is not unlawful. That argument should be rejected for the same reasons explained above. *See supra*, pp. 80-81.

II. THERE IS SUFFICIENT EVIDENCE FOR A JURY TO FIND THAT THE RICO MANUFACTURER DEFENDANTS ENGAGED IN A RICO CONSPIRACY

The RICO Manufacturer Defendants cursorily argue (Dkt. # 1930 at 21) that Plaintiffs have no evidence to prove a RICO/OCPA conspiracy. But Defendants misunderstand both the governing legal principles and the facts.

The RICO Manufacturer Defendants argue that "Plaintiffs must show 'the existence of an illicit agreement to violate the substantive RICO provision.'" Dkt. # 1930 at 20. While accurate, the RICO Manufacturer Defendants' authority ignores Supreme Court and Sixth Circuit guidance that: "[t]here is no requirement of some overt act or specific act in the [RICO] statute," and that "[a] conspirator must intend to further an endeavor which, if completed, would satisfy all of the elements of a substantive criminal offense, but it suffices that he [or she] adopt the goal of furthering or facilitating the criminal endeavor." *Salinas v. U.S.*, 522 U.S. 52, 63-66 (1997); *U.S. v. Rios*, 830 F.3d 403, 424 (6th Cir. 2016); *U.S. v. Patel*, 579 Fed. Appx. 449, 461 (6th Cir. 2014); *U.S. v. Fowler*, 535 F.3d 408, 420-21 (6th Cir. 2008).

So, contrary to the RICO Manufacturer Defendants' argument, to prove a RICO conspiracy (as opposed to a substantive RICO violation), Plaintiffs need only prove that the RICO Manufacturers[483] "intende[d] to further an endeavor" that satisfies all of the elements of the substantive RICO violation. The summary judgment record supports a finding of such intent because

[483] Summit TAC at ¶¶ 880, 890, and Cuyahoga TAC ¶¶ 923, 933, both identify the RICO conspirators as the RICO Manufacturers named in Summit and Cuyahoga's First Causes of Action, respectively.

it demonstrates that members of the Opioid Marketing Enterprise knew about and participated in the enterprise's common purpose to grow the market for prescription opioids through false marketing.

The summary judgment record also confirms that the RICO Manufacturer Defendants did more than just intend to further the RICO violations. Each of the Manufacturers named as RICO Defendants coordinated with the front groups and KOLs to disseminate false marketing messages. *See supra*, pp. 12-22. And the Manufacturers named as RICO conspirators also disseminated fraudulent branded marketing that furthered the enterprise's common purpose. *See supra*, pp. 8-12.

The RICO Manufacturer Defendants' cited cases are factually inapplicable. Moreover, the RICO Manufacturer Defendants ignore Supreme Court and the Sixth Circuit precedent concerning the proof necessary to prove a RICO conspiracy. Multiple cases recognize that participation in the actions of a RICO enterprise or the predicate acts of an enterprise supports the inference of a RICO conspiracy. *See Heinrich v. Waiting Angels Adoption Services, Inc.*, 668 F.3d 393, 411 (6th Cir. 2012) ("this agreement can be inferred from the individual defendants' involvement in the four well-pled predicate acts"); *Patel*, 579 F.3d. App'x at 461 ("A conspirator must intend to further an endeavor" and "may do this 'in any number of ways short of agreeing to undertake all of the acts necessary for the crime's completion'"); *Fowler*, 535 F.3d at 420 (defendant's participation in robbery and murder satisfied "the requirements for a RICO conspiracy conviction because it shows that he 'intended to further an endeavor which, if completed, would satisfy all of the elements of a substantive [RICO] offense'").

Here, the RICO Manufacturer Defendants took numerous actions that furthered the RICO violations committed by the Opioid Marketing Enterprise, such as coordination through the PCF, funding KOLs and front groups, and dissemination of their own branded marketing statements. *See supra*, pp. 8-22. These actions, taken together, are sufficient to defeat summary judgment.

Moreover, these facts move Plaintiffs' case well beyond the bounds of *United States v. Pinson*, 860 F.3d 152 (4th Cir. 2017). In *Pinson*, the government was only able to tie one common member

into what the court viewed to be four separate ventures, and therefore held that the government could not prove a single conspiracy because there was no "single-mindedness to achieve a particular goal." *Id.* at 162. Here, unlike *Pinson*, Plaintiffs have proved a single-mindedness towards achieving a particular goal. That there might have been some variation as to which RICO Manufacturer Defendants used which KOLs and front groups does not detract from their single-mindedness as to the conspiracy's common purpose.

III. THIS COURT HAS ALREADY DETERMINED THAT PLAINTIFFS' ALLEGATIONS SUFFICE TO PROVE RICO CAUSATION, AND THE SUMMARY JUDGMENT RECORD SUPPORTS PLAINTIFFS' ALLEGATIONS.

With respect to RICO causation, the RICO Defendants have largely recycled their Motion to Dismiss, arguing that Plaintiffs cannot prove proximate causation because the RICO Defendants' injurious conduct is too remote from Plaintiffs' injuries.[484] Dkt. # 1930 at 22-24. However, in ruling on the Motion to Dismiss, this Court already determined that Plaintiffs sufficiently alleged RICO proximate causation. *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2018 WL 6628898, at *4 (N.D. Ohio Dec. 15, 2018). Specifically, the Court rejected the causal chain proposed by Manufacturers and recognized that:

> Plaintiffs have alleged sufficient facts to support a far more direct chain of causation: (i) RICO Marketing Defendants made deceptive claims in promoting their opioids in order to sell more opioids than the legitimate medical market could support (**the conduct**); (ii) the excess opioids marketed by the RICO Marketing Defendants and distributed by the RICO Supply Chain Defendants were then diverted into an illicit, black market; (iii) Plaintiffs were forced to expend resources beyond what they had budgeted to attempt to stop the flow of the excess opioids into local communities and to bear the costs associated with cleaning them up (**the injury**).

Id. at *5 (emphasis in original). Further, the Court determined that Plaintiffs' claims do not disturb any of the underlying justifications for the proximate cause analysis, as outlined in *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258 (1992). *Id.* at *5.

[484] Plaintiff hereby incorporates their standing and causation arguments found in their Responses to Defendants' Motion to Dismiss, Dkt. # 654.

The Court's holding is consistent with Sixth Circuit precedent that, "[a]t bottom, . . . proximate cause is a 'flexible concept' and must be assessed on a case-by-case basis." *Wallace v. Midwest Financial & Mortg. Services, Inc.*, 714 F.3d 414, 420 (6th Cir. 2013). Indeed, the Sixth Circuit recently reiterated the flexibility of the proximate cause analysis, stating that "the definition of proximate cause is not a zero-sum game," and suggesting that "substantiality, directness, and foreseeability" are all relevant and overlapping considerations.[485] *Crosby v. Twitter, Inc.*, 921 F.3d 617, 624 (6th Cir. 2019).

As the facts outlined above make clear, Plaintiffs have ample evidence to demonstrate that the RICO Defendants' actions and inactions were a substantial factor in causing the opioid epidemic, which caused Plaintiffs to expend resources beyond what they had budgeted to attempt to stop the excess flow of opioids into local communities and to clean them up. *See In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898 at *5. Plaintiffs separately filed an Opposition to Manufacturer Defendants' Motion for Summary Judgment on Causation. *See* Plaintiffs' Cosolidated Mem. in Opp. to Defendants' Mots. for Summary Judgment on Proof of Causation (PSJ2). In that Opposition, Plaintiffs argue that each Manufacturer Defendant, through a deceptive and illegal marketing campaign and a failure to prevent diversion of its prescription opioids, caused sharply increased harms and costs from both licit and illicit opioid use in the Plaintiff Counties. Plaintiffs demonstrate this causal connection with both statistical analysis of aggregate evidence by prominent public health economists and more individuated proof that each Defendant's intentional and negligent conduct was expected to and did cause these extensive harms. Plaintiffs incorporate those arguments herein by reference.

Moreover, Plaintiffs have demonstrated that their injuries are and were the foreseeable result of the Defendants' conduct under the standard articulated in *Bridge v. Phoenix Bond & Indemnity Co.*,

[485] The OCPA does not require a direct injury. *See* Ohio Rev. Code § 2923.34(A) ("Any person who is injured or threatened with injury by a violation of section 2923.32 . . . may institute a civil proceeding"). Unlike RICO, which requires an "injur[y] . . . by reason of a violation of 1962," the OCPA omits the "by reason of" requirement. Instead, the OCPA states that a plaintiff who is "directly or indirectly injured by conduct in violation of section 2923.32, . . . shall have a cause of action." *See* Ohio Rev. Code § 2923.34(E); *see also* 1 CV Ohio Jury Instructions 445.03.

553 U.S. 639, 655-58 (2008). The *Bridge* Court rejected the argument that RICO plaintiffs must show "first-party reliance" to satisfy the proximate-cause principles articulated in *Holmes*. *Id.* at 657-58; *accord In re Nat'l Prescription Opiate Litig.,* No. 1:18-OP-45090, 2018 WL 4895856, at *14 (N.D. Ohio Oct. 5, 2018). Instead, the inquiry should be on whether the injury was a "foreseeable and natural consequence of petitioners' scheme." *Bridge,* 553 U.S. at 658. Here, Plaintiffs' injuries are and were the foreseeable result of the Defendants' conduct. It was foreseeable that the economic burden of an increase in addiction would fall on the public entities that are obligated to provide law enforcement, emergency health, and other social welfare services to their communities. This precise harm was foreseeable and was among the harms the CSA was expressly designed to avoid, and Defendants knew and ignored the foreseeable and natural economic consequences of their enterprises. Indeed, the evidence suggests Defendants tolerated and even encouraged diversion and illicit use, knowing its inevitable toll on the Plaintiffs' resources, as part and parcel of their common mission to expand the demand for opioids and then satisfy that demand with unrestrained supply.

A. Independent Actions Do Not Break the RICO Chain of Causation

1. The RICO Defendants have not demonstrated that any intervening or superseding causes were unforeseeable

Apparently recognizing the link between Defendants' conduct and Plaintiffs' injuries, as they must, the RICO Defendants assert an affirmative defense: that Plaintiffs' injuries were caused by an intervening or superseding cause (other actors) and, relatedly, that it is impossible to determine whether Plaintiffs' injuries were caused by the RICO Defendants' collective racketeering acts or by the independent conduct of each actor. Dkt. # 1930 at 23; Dkt. # 1904 at 14-16. As a threshold issue, defendants bear the burden of proof that an intervening or superseding cause breaks the chain of causation, meaning that, in order to prevail on summary judgment, defendants must affirmatively demonstrate that there is no issue of fact. *See Brune & Ashing v. Basf Corp.*, 234 F.3d 1267 (6th Cir.

2000) (overturning award of summary judgment where defendant failed to meet its burden of proving intervening cause); *see also In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 75 (1st Cir. 2013).

"According to the general principles of tort law . . . an intervening act must be unforeseeable in order to break the causal connection and therefore relieve a defendant of all liability for its negligence."[486] *Harris v. St. Vincent Med. Ctr.*, 205 F.3d 1340, at *3 (6th Cir. 2000). "The question is *not* whether an [intervening or superseding] act is criminal. The correct question is whether the act is foreseeable." *Nat'l Credit Union Admin. Bd. v. Ciuni & Panichi, Inc.*, No. 5:16-CV-455, 2019 WL 188472, at *16 (N.D. Ohio Jan. 11, 2019). "Further, an intervening act is deemed to be a superseding cause which breaks the chain of causation only if the intervening act is not brought into operation by the original wrongful act, but operates entirely independently thereof; it must be such a cause as would have produced the result, without the co-operation of the original wrong." *Id.* (internal quotations omitted). Thus, the RICO Defendants cannot argue that intervening or superseding actions break the chain of causation where, as here, they *contemplated* and *intentionally caused* the allegedly intervening acts. *See, e.g.*, *In re Neurontin*, 712 F.3d at 39; *see also In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633, 645 (3d Cir. 2015); *see also* Restatement (Second) of Torts § 447.

What is more, some of the alleged intervening conduct bears only on the question of damages, not on causation. *In re Neurontin*, 712 F.3d at 39. Relatedly, ample case law supports the proposition that an injury may have more than one producing cause. *See, e.g., Trollinger v. Tyson Foods, Inc.,* 370 F.3d 602, 620 (6th Cir. 2004) ("[P]laintiffs need not show that [a defendant's] conduct was the sole cause of their injury in order to establish proximate cause; they need show only that the conduct was a substantial cause.").

[486] "The Sixth Circuit has stated that Civil RICO is a statutory tort, so causation principles that generally apply in tort cases apply in civil RICO cases." *James v. Meow Media, Inc.*, 90 F. Supp. 2d 798, 818 (W.D. Ky. 2000), *aff'd,* 300 F.3d 683 (6th Cir. 2002) (citing *Kaufman v. BDO Seidman*, 984 F.2d 182, 185 (6th Cir.1993)). The cases cited herein examine Ohio causation principles, and "[o]ther state courts within [the Sixth Circuit] also accept these general rules." *Harris*, 205 F.3d at *3.

The RICO Manufacturer Defendants' arguments that the actions of others – other defendants, doctors, and the DEA – break the chain of causation lack merit. First, as the law above makes clear, the RICO Defendants cannot argue that doctors break the chain of causation, because the very purpose of Defendants' enterprise was to make money by flooding the market with prescription pain pills. *See supra*, pp. 3, 7-8, 27-28, 31-42, 51, 54-63. The RICO Defendants also specifically sought to change physician prescribing standards, encouraging doctors to prescribe opioids more liberally. *See supra*, 11-22, 25-27. Thus, to the extent doctors' prescriptions of opioids bear on causation, the RICO Defendants necessarily foresaw – and intended – that their actions and inactions would influence prescribing behavior. *Harris*, 205 F.3d at *3. Nor can the Defendants' acts be said to be entirely independent from the actions of the doctors whom they influenced. *Id.* Therefore, doctors are not intervening actors.

The very same is true with respect to the DEA, whom the RICO Defendants worked together to mislead, influence, and to prevent from putting an end to Defendants' very profitable racketeering activity. *See supra*, pp. 30-51, 53-64, 66-73.

Finally, although the RICO Defendants insinuate that the independent conduct of other defendants breaks the causal chain, they have not made the argument specific, identifying the individual (or class of individuals) who they assert took independent action, or even what that action was. Dkt. # 1930 at 23. Nor have they proffered any actual evidence. At this stage, viable arguments require more. Further, Plaintiffs' evidence shows that the RICO Defendants worked together, and the law makes all actors in a RICO conspiracy liable for the actions of co-conspirators. *Salinas*, 522 U.S. at 64 ("If conspirators have a plan which calls for some conspirators to perpetrate the crime and others to provide support, the supporters are as guilty as the perpetrators.").

2. The cases cited by the RICO Manufacturer Defendants are inapplicable

The RICO Defendants' proffered case law is easily distinguishable. For example, *Wethington v. Purdue Pharma LP*, 218 F.R.D. 577 (S.D. Ohio 2003) did not hold that intervening actors preclude a

finding of proximate causation, but was a class certification case in which the court found the learned intermediary doctrine prevented commonality. Because this is not a failure to warn case, the learned intermediary doctrine is inapplicable. Likewise, *Saro v. Brown,* 11 Fed. Appx. 387, 388-89 (6th Cir. 2001), in which the Sixth Circuit dismissed as frivolous an inmate's *pro se* RICO and unjust enrichment case against his former attorney for failing to file a motion to alter the criminal judgement against the inmate, is woefully inapposite. The court recognized that the inmate had failed to allege *any* "direct or inferential allegations." *Id.* at 388. Finally, the RICO Defendants cite third-party-payor cases that this Court has already considered and rejected. Dkt. # 1930 at 23 (citing *Sidney Hillman Health Center of Rochester v. Abbott Laboratories*, 873 F.3d 574 (7th Cir. 2017) and *Sergeants Benevolent Ass'n Health and Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305 (E.D.N.Y. 2014)); *see* Mfr. Reply to Plaintiffs' Opposition to Motion to Dismiss, Dkt. # 746 at 9 (citing *Sidney Hillman*); *see In re Nat'l Prescription Opiate Litig.,* 2018 WL 6628898, at *6.

Relatedly, the RICO Defendants rely upon the district court decision in *Sergeants Benevolent Ass'n Health and Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71 (2d Cir. 2015) to challenge causation, but on appeal, the court held that Plaintiffs may use circumstantial evidence to infer that doctors relied upon defendants' misrepresentations – broadly, with respect to every doctor. *See id.* at 88-89. To the extent that the Court believes doctors' decisions and actions may have impacted the chain of causation, the Court should allow a jury to decide whether the RICO Defendants' actions of corrupting entire areas of scientific literature and "educational" material directed at physicians and altering the medical standards governing their practice *effectively* reduced doctors' prescribing decisions such that those decisions cannot be causal. *See id.* at 88.

3. The RICO Distributor Defendants' arguments lack merit

First, the RICO Distributor Defendants assert that they committed no predicate acts in the causal chain, but the Court has already dispensed with this argument because the Distributor Defendants violated the CSA. *In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at *11. Moreover,

it is not necessary that all or any one of the RICO Distributor Defendants committed any predicate act themselves – although they did – because the RICO Distributor Defendants were part of the RICO conspiracy. *Salinas*, 522 U.S. at 64 ("The RICO conspiracy statute, § 1962(d), broadened conspiracy coverage by omitting the requirement of an overt act; it did not, at the same time, work the radical change of requiring the Government to prove each conspirator agreed that he would be the one to commit two predicate acts."). Further, "[w]hether a single conspiracy or multiple conspiracies have been shown is a question of fact resolved by the jury." *United States v. Hughes*, 895 F.2d 1135, 1140 (6th Cir. 1990).

Second, the RICO Distributor Defendants contend that Plaintiffs can only prove RICO causation if they can prove that the DEA or the Ohio Board of Pharmacy would have acted had the RICO Distributor Defendants properly reported suspicious orders. But that argument entirely ignores that Distributor Defendants flatly failed in their obligation *not to ship* suspicious orders, which would have, in and of itself, prevented Plaintiffs' injury. *See* 21 C.F.R. § 1301.74; 21 U.S.C. § 823(b). At best, Distributor Defendants argue that Plaintiffs' injury has more than one cause. *Trollinger v. Tyson Foods, Inc.,* 370 F.3d 602, 620 (6th Cir. 2004) ("[P]laintiffs need not show that [a defendant's] conduct was the sole cause of their injury in order to establish proximate cause; they need show only that the conduct was a substantial cause."). Further, the RICO Distributor Defendants cannot argue that intervening or superseding actions break the chain of causation here where they *contemplated* and *intentionally caused* the allegedly intervening acts; in that circumstance, the original tortfeasors remain liable for the consequences of their actions. *See, e.g.*, *In re Neurontin*, 712 F.3d at 39. As the facts above demonstrate, the RICO Distributor Defendants worked to prevent the DEA from stopping their racketeering. *See supra,* pp. 30-51.

The RICO Distributor Defendants reach for district court cases outside the Sixth Circuit to attempt to make the alleged discretionary nature of DEA intervention an issue of law, but even those

cases fail. Dkt. # 1904 at 14-15. The court made clear in *Dow Chem. Co. v. Exxon Corp.*, 30 F. Supp. 2d 673, 696 (D. Del. 1998) that proximate cause failed because there were *multiple*, *highly influential* potentially intervening factors – not just the alleged discretion of the government agency. Likewise, in both other cases cited by the RICO Distributor Defendants on this point the courts determined that proximate cause did not exist because there were a number of possible intervenors and potentially influential intervenors, which is not the case here. *See Barr Labs., Inc. v. Quantum Pharmics, Inc.*, 827 F. Supp. 111, 116 (E.D.N.Y. 1993); *Lifschultz Fast Freight, Inc. v. Consol. Freightways Corp. of Delaware*, 805 F. Supp. 1277, 1291 (D.S.C. 1992).

Finally, the RICO Distributor Defendants argue (Dkt. # 1904 at 12) that whether an order is "suspicious" is a subjective and disputed question of fact. Assuming *arguendo* that defendants are correct, that is yet a further reason why summary judgment on the issue of causation is not appropriate.

IV. PLAINTIFFS HAVE ESTABLISHED RICO AND OCPA INJURIES FOR WHICH DAMAGES ARE AVAILABLE

A. Plaintiffs' Injuries Are Recoverable Monetary Injuries Under RICO and OCPA

RICO provides that civil damages are available to a plaintiff "injured in his business or property." 18 U.S.C. § 1964(c). The RICO Manufacturer Defendants assert (Dkt. # 1930 at 25), citing *Jackson v. Sedgwick*, 731 F.3d 556, 565-66 (6th Cir. 2013), that some of Plaintiffs' damages stem from personal injuries to county residents and are therefore not injuries to "business or property" within the meaning of RICO. Defendants misconstrue the nature of Plaintiffs' damages. Plaintiffs seek to recover their own monetary losses; they do not seek to recover county residents' economic losses stemming from personal injury. *Jackson*, therefore, does not preclude recovery here. Indeed, this Court has already addressed and rejected this precise argument. *In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at *8-9 (N.D. Ohio Dec. 19, 2018). The RICO Defendants have not identified any basis for relitigating that issue.

In *Jackson*, former employees sued their employer's third-party workers' compensation claims administrator, alleging that the administrator formed an association-in-fact enterprise with a "cut-off" doctor to avoid paying workers' compensation benefits that were due. 731 F.3d at 558. The Sixth Circuit affirmed dismissal of the complaint, holding that plaintiffs failed to plead an injury to "business or property" recoverable under 18 U.S.C. § 1964(c). 731 F.3d at 558-59; *id.* at 562. The Court explained that, "the phrase 'business or property' . . . exclude[s] personal injuries suffered." *Id.* at 564. "Congress must have intended to exclude some class of injuries by the phrase 'business or property' when it enacted RICO," *id.* at 564 (quoting *Reiter v. Sonotone*, 442 U.S. 330, 339 (1979)) (internal quotation marks omitted), and "[a] personal injury . . . is different in kind from an injury to 'business or property.'" *Id.* at 564. Because workers' compensation benefits provide compensation for personal injury, "those benefits merely reflect the pecuniary losses associated with the personal injury," and are therefore not recoverable under RICO. *Id.* at 566.

Significantly, however, the Supreme Court has recognized that "money, of course, is a form of property." *Reiter*, 442 U.S. at 338. For that reason, the Sixth Circuit has held that a "monetary injury, standing alone, may be injury in one's 'property.'" 731 F.3d at 564 (quoting *Reiter*, 442 U.S. at 339-40) (internal quotation marks omitted); *see also In re Nat'l Prescription Opiate Litig.,* 2018 WL 6628898, at *7 ("As a general principal, 'money, of course, is a form of property.'" (citing *Reiter*)); *Iron Workers Local Union No. 17 Ins. Fund & its Trustees v. Philip Morris Inc.,* 29 F. Supp. 2d 801, 821 (N.D. Ohio 1998) ("concrete financial loss" is injury to business or property); *see also County of Oakland v. City of Detroit*, 866 F.2d 839, 845 (6th Cir. 1989) ("A person whose property is diminished by a payment of money wrongfully induced is injured in his property."). In distinguishing between non-redressable personal injuries and redressable injuries to property, the Sixth Circuit clarified that damages are excluded only when they "aris[e] directly out of" a personal injury. *Jackson*, 731 F.3d at 565-66.

Plaintiffs have identified thirteen categories of monetary loss that qualify as an injury to their "property" within the meaning of RICO, which this Court has summarized into three general categories: "(1) public expenditures made in direct response to opioid use and trafficking; (2) reduced tax revenue resulting from that abuse, misuse, and addiction; and (3) losses caused by diminished property values." *In re Nat'l Prescription Opiate Litig.*, No. 1:18-OP-45090, 2018 WL 4895856, at *15 (N.D. Ohio Oct. 5, 2018); *see also In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at *7. None of those categories of monetary loss seek to recover damages for personal injuries suffered by Plaintiffs.

The RICO Defendants mistakenly suggest (Dkt. # 1930 at 25-26) that because some of Plaintiffs' monetary losses may "flow from" providing healthcare service to county residents, those losses arise directly out of personal injuries and are therefore not recoverable under *Jackson*. But even assuming some of Plaintiffs' damages seek to recover monetary losses for extra healthcare services, none of those damages seek to recover for county residents' economic losses arising out of their personal injuries. As this Court has already recognized, Plaintiffs' damages claims are solely premised on economic losses to the counties themselves; there is no claim that the counties suffered personal injury. *See* Dkt. # 1203 (Polster Op.) at 15. This case, therefore, is distinguishable from *Jackson*, and summary judgment is not appropriate.

Finally, there is no question that Plaintiffs' damages are recoverable under the OCPA, which, unlike RICO, does not limit recovery to injuries to "business or property." *See* Ohio Rev. Code. § 2923.34(A) (damages are recoverable by "[a]ny person who is injured or threatened with injury by a violation of section 2923.32"); *cf. Bradley v. Miller*, 96 F. Supp. 3d 753, 774 (S.D. Ohio 2015) (recognizing that OCPA allows broader recovery than RICO).

B. Damages For Injuries Resulting From Branded Marketing Are Not Precluded As A Matter Of Law

The RICO Defendants likewise seek to preclude recovery as a matter of law for any damages that might result from the RICO Manufacturers' branded marketing on the basis that branded marketing is competitive conduct and therefore cannot constitute enterprise conduct. Dkt. # 1930 at 24 (branded marketing is "the independent action of a Manufacturer trying to gain sales at the expense of other Manufacturers"). That is incorrect as a matter of law.

Liability under RICO is premised on the existence of an injury caused by *conduct* of an enterprise. 18 U.S.C. § 1962(c). As explained above, the RICO Marketing Enterprise pursued the common purpose of expanding the prescription opioid market, and Plaintiffs have provided substantial evidence of that conduct, to include branded advertising. Each of the RICO Manufacturer Defendants engaged in marketing to advance the Marketing Enterprise's common purpose of expanding the prescription opioid market by, *inter alia*, misrepresenting that opioids were non-addictive or by fraudulently downplaying the risk of abuse or addiction. *See supra*, pp. 7-9, 11-12.

Because the RICO Manufacturer Defendants' marketing, both branded and unbranded, sought to expand the market for prescription opioids—a purpose the RICO Defendants do not deny—it is properly included as *enterprise* conduct because it advances the Marketing Enterprise's common purpose. *See, e.g., United States v. Turkette*, 452 U.S. 576, 583 (1981) (an association-in-fact enterprise is "a group of persons associated together for a common purpose of engaging in a course of conduct"). That the same conduct might also have had a secondary, competitive purpose—to increase a particular manufacturer's market share—does not insulate the *conduct* under RICO. *Cf. Sedima S.P.R.L. v. Imrex Co., Inc.* 473 U.S. 479, 497 (1985) ("the essence of the violation is the commission of [the predicate] acts in connection with the conduct of the enterprise").

The RICO Manufacturer Defendants cite no authority for the proposition that conduct in support of an enterprise's affairs may not be considered as a matter of law whenever such conduct

also furthers the individual participant's affairs vis-à-vis the other enterprise participants. Defendants' invocation of *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993), which concerned conduct that was alleged to be solely on behalf of an individual's "own affairs," is therefore legally inapposite here. Nor do Defendants cite any authority to support their suggestion that competitive conduct *per se* is exempt from liability under RICO. Indeed, were Defendants' interpretation of the law correct, damages under RICO would be unavailable in the precise circumstances where the participants have the greatest incentive to form an enterprise: where conduct is mutually beneficial to both the enterprise and to the individual participants.

COMMON LAW CIVIL CONSPIRACY ARGUMENT

Under Ohio law, a civil conspiracy requires proof of: "(1) a malicious combination; (2) [between] two or more persons; (3) injury to person or property; and (4) existence of an unlawful act independent from the actual conspiracy." *In re: Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at *11 (citation and internal quotation marks omitted).[487]

Defendants move for summary judgment on the ground that Plaintiffs have failed to offer any evidence on the first prong of civil conspiracy, malicious combination, arguing there is "no evidence" to demonstrate "an agreement to achieve an unlawful objective." Dkt. # 1692 at 1-2, 5. *See also* Dkt. # 1716 at 7-6; Dkt. # 1930 at 20-21.

[487] *Accord, Lee v. Countrywide Home Loans, Inc.*, 692 F.3d 442, 446 (6th Cir. 2012). The "malice" required is simply "that state of mind under which a person does a wrongful act purposely, without a reasonable or lawful excuse, to the injury of another." *Williams v. Aetna Fin. Co.*, 700 N.E.2d 859, 868 (Ohio 1998). *Gosden v. Louis*, 687 N.E.2d 481, 496 (Ohio Ct. App. 1996) (malice may "be inferred from… the underlying tort and need not be proven separately or expressly.") The "unlawful act" is satisfied by the commission of an underlying tort in furtherance of the conspiracy. *Gosden*, 687 N.E.2d at 496-497; *In re: Nat'l Prescription Opiate Litig.,* 2018 WL 6628898, at *11. "[T]he unlawful acts of any one member of the conspiracy will satisfy the 'underlying unlawful act' requirement," and the act does not need to be jointly committed. *Hale v. Enerco Group, Inc.*, No. 1:10 CV 00867-DAP, 2011 WL 49545, at *5 (N.D. Ohio Feb. 11, 2011).

I. THERE IS A GENUINE DISPUTE OF MATERIAL FACT REGARDING MANUFACTURERS', DISTRIBUTORS', AND PHARMACIES' AGREEMENT TO ENGAGE IN A CONSPIRACY TO GROW THE OPIOID MARKET AND AVOID REGULATORY ENFORCEMENT TO EFFECTUATE THAT GOAL

To establish a "malicious combination," Plaintiffs need not prove "an explicit agreement[,]" *Lee*, 692 F.3d at 446. As this Court has already held, in this case:

> [Proving] … the existence of a malicious conspiracy requires "**only a common understanding or design, even if tacit, to commit an unlawful act**." *Gosden v. Louis*, 687 N.E.2d 481, 496-98 (Ohio Ct. App. 1996). "**All that must be shown is that...the alleged coconspirator shared in the general conspiratorial objective**." *Aetna Cas. & Sur. Co. v. Leahey Const. Co., Inc.*, 219 F.3d 519, 538 (6th Cir. 2000) (citation and internal quotation marks omitted).

In re: Nat'l Prescription Opiate Litig., 2018 WL 6628898, at *11 (emphasis added); *accord United States v. Murphy*, 937 F.2d 1032, 1039 (6th Cir. 1991). Plaintiffs simply must show "that there was a single plan, that the alleged coconspirator shared in the general conspiratorial objective, and that an overt act was committed in furtherance of the conspiracy that caused injury to the complainant." *Hooks v. Hooks*, 771 F.2d 935, 944 (6th Cir. 1985).

The "tacit agreement" underpinning the conspiracy may be inferred from "circumstantial evidence." *Maggiore v. Bradford*, 310 F.2d 519, 521 (6th Cir. 1962); *accord Gosden*, 687 N.E.2d at 496 ("[N]ot even a meeting is necessary" to establish an agreement; "it is sufficient that the parties in any manner come to a mutual understanding that they will accomplish the unlawful design."); *Weberg v. Franks*, 229 F.3d 514, 528 (6th Cir. 2000) ("Rarely in a conspiracy case will there be direct evidence of an express agreement among all the conspirators to conspire, ... circumstantial evidence may provide adequate proof of conspiracy.")

The existence of a tacit agreement based on circumstantial evidence is a highly factual inquiry. Summary judgment is rarely appropriate in civil conspiracy claims. *See Murphy*, 937 F.2d at 1039; *Lee*, 692 F.3d at 446 ("The ultimate fact of conspiracy is solely a question for the jury, unless the court can say, as a matter of law, that there is *no proof* tending to establish a conspiracy.") (emphasis added).

The decision in *Direct Sales Co. v. U.S.*, 319 U.S. 703 (1943), which the DEA provided to many of the Defendants as part of the Distributor Initiative in or around 2005 and again later in 2015, [488] is instructive. In *Direct Sales*, the Court found that defendants entered into a conspiracy to excessively and illegally distribute and sell prescription opioids in violation of federal law based on "a tacit understanding, created by a long course of conduct and executed in the same way." 319 U.S. at 714. The Court cited opioids' highly controlled and dangerous status, defendants' repeated violations of the law, "abnormal increases in the size of the buyer's purchases," and the "volume, frequency and prolonged repetition" of the outsized opioid sales as "circumstantial evidence" sufficient to establish the conspiracy. *Id.* at 710-711, 714.

The summary judgment record here establishes a genuine issue of material fact as to whether Defendants shared a "general conspiratorial objective to expand[] the opioid market" and to "disregard" regulatory obligations, including "drug reporting," in order to "effectuate that goal." *In re: Nat'l Prescription Opiate Litig.,* 2018 WL 6628898, at *11. That there was, at a minimum, a tacit agreement among all three categories of Defendants is borne out by their extensive communications, coordinated failures to implement effective controls against diversion, and their common actions to circumvent and obstruct DEA regulatory activity.

A. The Summary Judgment Record Demonstrates That Manufacturers Entered into an Agreement to Grow and Maintain the Opioid Market That Goes Beyond Independent Conduct or Supposition

The Manufacturer Defendants contend that Plaintiffs cannot prove a malicious agreement. Dkt. # 1930 at 20-21. However, as shown above, the summary judgment record demonstrates that the Manufacturer Defendants shared in a general conspiratorial objective to expand the opioid market.

Here, unlike *Hensley v. Gassman,* 693 F.3d 681 (6th Cir. 2012), where there was only evidence of independent conduct, the summary judgment record demonstrates that the Manufacturer

[488] Many Defendants, including Walmart, H.D. Smith, AmerisourceBergen, and Cardinal had the *Direct Sales* decision in their files and produced it in this litigation. *See* Exh. 667, WMT_MDL_000043650; Exh. 668, HDS_MDL_00002782; Exh. 210, ABDCMDL00315887; Exh. 669, CAH_MDL_PRIORPROD_DEA07_01178176-R.

Defendants, including generic manufactures, all worked together to increase and maintain the opioid market through the common practice of disseminating false marketing representations about opioids in general and about their own branded products. *See supra*, pp. 77-82.

Evidence of an agreement may also be found in Manufacturer Defendants' efforts to work with distributors and pharmacies to reroute supply of opioids after regulatory actions, despite indicators of diversion. *See supra*, pp. 72-73. Manufacturer Defendants, too, worked with the distributors and pharmacies to turn a blind eye to regulatory violations and to keep opioids flowing. *See supra*, pp. 38-42.[489]

Similarly, unlike *Woodward Const., Inc. v. For 1031 Summit Woods, L.L.C.,* 30 N.E. 3d 237, 244 (Ohio Ct. App. 2015), which Manufacturers misleadingly quote,[490] the evidentiary record confirms that Defendants "directed, solicited, and knew" of each other's actions and the actions of the KOLs and front groups who disseminated their messages. Thus, Plaintiffs have amply demonstrated knowledge and coordinated actions that contributed to the goal of the Defendants' conspiracy to grow the opioid market.

B. The Summary Judgment Record Demonstrates That The Distributor and Pharmacy Defendants Entered into The Agreement to Increase and Maintain the Opioid Market by Selling Extraordinary Quantities of Opioids While Disregarding Regulatory Obligations.

The Distributor and Pharmacy Defendants contend that there is no evidence they shared a "common understanding or design" to protect and grow the opioid market by "disregarding" regulatory obligations[491] because: (a) there is no evidence they agreed not to report and halt suspicious orders or coordinate their distribution practices (Dkt. # 1692 at 14-20; Dkt. # 1716 at 4-5); (b) their

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[489] *See* Exh. 663, MNK-T1_0005639179 (For example, when Walgreens ceased self-distribution because it understood the DEA was about to shut down yet another Walgreens distribution center for breaching CSA duties, Mallinckrodt put "all hands-on deck" to reroute Walgreens opioid shipments through Cardinal and Anda.)

[490] *See* Dkt. # 1930 at 22. Manufacturers' quote from *Woodward Const.*, omits critical portions of that decision which make clear that the information missing from that case was evidence that the conspirators "directed, solicited, or knew of Fletcher's actions." *Woodward,* 30 N.E. 3d at 244.

[491] *In re: Nat'l Prescription Opiate Litig.,* 2018 WL 6628898, at *11.

actions were merely parallel conduct and cannot form the basis for inferring a conspiracy (Dkt. # 1716 at 14-17), and (c) there is no evidence they fraudulently marketed opioids (Dkt.# 1692 at 10-14; Dkt. # 1716 at 2-4). The Distributor and Pharmacy Defendants are incorrect. The record demonstrates that the Distributor and Pharmacy Defendants shared a common agreement to disregard their regulatory obligations in order to protect and grow the opioids market.

1. The Evidence Shows Distributors and Pharmacies Coordinated Regarding Their Shared Objective

The record shows the Pharmacy and Distributor Defendants engaged with the RICO Supply Chain Defendants in substantially the same coordinated activities. The RICO Supply Chain Distributors used their dual membership in the HDA and NACDS and their distribution relationships with the Pharmacies to join the Pharmacy Defendants into the Conspiracy. Through membership and leadership positions in the NACDS and their relationships with the RICO Supply Chain Distributors, the Pharmacy Defendants coordinated to grow and protect the Opioid Supply Chain, including through disregard of their CSA duties. *See supra*, pp. 27-73.

The Pharmacy Defendants coordinated with the RICO Supply Chain Defendants and Distributors in 2007 and 2008 to convince the DEA that the industry was working together to develop guidelines that would improve the industry's compliance with the CSA and its implementing regulations. *See supra*, pp. 42-47. Like the Distributor Defendants, the Pharmacy Defendants also had no intention to implement or comply with the ICGs but rather sought to divert attention from their regulatory non-compliance. *See supra*, pp. 42-47, 53-58, 59-73.

Similarly, the RICO Defendants' plan to "gang up on DEA,"[492] was extended to, and agreed upon, by the Pharmacy and Distributor Defendants. The Pharmacy and Distributor Defendants coordinated through the NACDS and HDA to support the Marino Bill, which further protected the supply chain by limiting the DEA's enforcement authority. *See supra*, pp. 47-51. The Pharmacy and Distributor Defendants additionally opposed legislative efforts, both nationally and in Ohio, that

[492] *See, supra,* at p. 34-83, Exh. 252, HDS_MDL_00086622; Exh. 253, CAH_MDL2804_00851292.

would potentially inhibit excess opioids distribution or provide regulators with greater anti-diversion resources. *See supra,* pp. 47-51.

Through the NACDS, the Pharmacy and Distributor Defendants further coordinated to subvert their CSA duties, forming, *inter alia*, a "coalition" on controlled substances to "ensure that any imposed restrictions regarding the continued distribution of controlled substances are not performed in an overly broad manner" and working in partnership with HDA to "[d]evelop … solutions to the [DEA] enforcement issues" and "develop strategies" concerning "ongoing problems that NACDS members are having with DEA enforcement actions." *See supra*, pp. 53-58.

The Pharmacy and Distributor Defendants additionally coordinated through their mutual supply of the same chain pharmacies. These Defendants shielded each other from DEA attention, misrepresenting each other's compliance, working to manipulate SOM parameters in order to prevent rising and noncompliant sales from coming to the DEA's attention, and providing each other preferential treatment. *See supra*, pp. 59-73. Many of the same noncompliant tactics developed in the course of the relationship between the Distributor Defendants and the Pharmacy Defendants were carried over into their individual SOM practices. *See supra*, pp. 64.[493]

The Pharmacy and Distributor Defendants' claims that they were coordinating to prevent diversion is refuted by the clear evidence that, in reality, these Defendants failed to implement effective controls, severely underreported suspicious orders, and continued to ship.[494] None of the Pharmacy or Distributor Defendants complied with their CSA obligations to maintain effective controls against diversion, report suspicious orders, or halt suspicious shipments.[495]

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[493] *See* Exh. 565, WAGMDL00667936 (systems were also adopted by self-distributing Pharmacies in their own internal SOM systems to "avoid" having to "report a SOM to the DEA.")

[494] *See* Rafalski Rep., Dkt. # 2000-22 at 40-186 and Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Judgment Adjudication that Defendants Did Not Comply with Their Duties Under the Federal Controlled Substances Act to Report Suspicious Orders and Not Ship Them ("CSA – Compliance"), Dkt. # 1924.

[495] *See* CSA - Compliance, Dkt. # 1924, Rafalski Rep., Dkt. # 2000-22 at 46-185, Whitelaw Rep., Dkt. # 2000-26 at 44-48.

Defendants' deliberate failures to report and failures to halt suspicious orders were both to shield their business from the DEA's attention and to convince the DEA that growing shipments of opioids had been reviewed and were not likely to lead to diversion, in support of the growing opioid market. *See supra*, pp. 37-38.

Thus, the record demonstrates that the coordinated efforts of the RICO Supply Chain Defendants extended to the Pharmacy and other Distributor Defendants as well. These Defendants worked together through a variety of forums, including direct interaction and coordination through the NACDS and HDA. From this evidence of same or similar conduct regarding failure to comply with CSA duties, constant communication and coordination between Defendants, both directly and through trade groups, a jury could reasonably conclude that, like the RICO Supply Chain Defendants, the Pharmacy and Distributor Defendants' actions were more than just independent, parallel conduct, but instead are consistent with the existence of a conspiracy to protect the supply chain and the resulting profits. There is, at a minimum, sufficient evidence from which a jury could find a tacit agreement to grow and maintain the expanded opioid market.

The cases cited by Defendants are inapposite, and largely concern factually distinct and non-analogous failures to present evidence[496] and deficiencies in pleadings on motion to dismiss.[497]

2. Defendants' Near Uniform CSA Noncompliance, Including Failure to Report Suspicious Orders, Is Not Merely Parallel Conduct, but Show Defendants' Common Understanding.

Like the RICO Supply Chain Defendants, the Pharmacy and Distributor Defendants argue that any failures to comply with the CSA, including failures to halt and report suspicious orders, were

[496] *Bergin Fin. Inc. v. First Am. Title Co.*, 397 F. App'x 119 (2010) (no evidence alleged conspirator knew of or agreed to fraud); *Robertson v. Lucas*, 753 F.3d 60 (6th Cir. 2014) (no evidence of agreement to deprive rights or that rights were violated); *Castaneda De Esper v. Immigration and Naturalization Service*, 557 F.2d 79, 84 (6th Cir. 1977) (failure to reveal a conspiracy not a statutory ground for deportation).

[497] *Moore v. Johnson & Johnson*, 907 F. Supp. 2d 646 (E.D. Pa. 2012) (plaintiff failed plead any agreement to work in concert or to act in a manner contrary to the law); *State ex rel. Jennings v. Purdue Pharma L.P.*, No. CVN18C01223MMJCCLD, 2019 WL 446382, at *14 (Del. Super. 2019) (plaintiff failed to plead elements of conspiracy).

merely parallel conduct and not evidence of conspiracy. (Dkt. # 1716 at 14; Dkt. # 1692 at 16). The Pharmacy and Distributor Defendants are also incorrect.[498]

The evidence shows that the Pharmacy and Distributor Defendants' near universal noncompliance with their regulatory duties to effectively monitor, report, and halt suspicious orders[499] was not merely unrelated parallel action but was in service of a "common understanding or design" to disregard CSA compliance obligations to grow and maintain the opioid market. *Gosden*, 687 N.E.2d at 496-98.

There is ample evidence, described above, from which a jury could reasonably conclude that the Pharmacy and Distributor Defendants agreed about their approach to suspicious order monitoring through multiple avenues, including: direct interactions that indicated the Pharmacy and Distributor Defendants had agreed to mutually support each other in avoiding SOM parameters and not reporting suspicious orders, and efforts through their trade groups like the NACDS and HDA to avoid and prevent DEA scrutiny. *See supra,* pp. 27-73. Each Pharmacy and Distributor Defendant failed to report suspicious orders in similar ways.[500] This is sufficient evidence from which a jury could reasonably infer that there was at least a tacit agreement.

Pharmacy Distributors who supplied their own chain pharmacies and the Distributors engaged to provide additional supply to the same chain pharmacies knew they were each filling suspicious orders placed by the chain pharmacies they both serviced, and yet failed to report each other's known suspicious orders. *See supra,* pp. 59-73. The Distributor Defendants argue that they have no duty to report each other's misconduct. (Dkt. 1692 at 18-19). However, Defendants' failure to report each other's known violations is not the basis for liability here, but rather is evidence of Defendants' common understanding and agreement. *See Javitch v. Capwill*, No. 3:01 CV 7371, 2011 WL 1002744, *3

[498] Plaintiffs incorporate here the arguments made at page 88 above in response to similar arguments made by the RICO Supply Chain Defendants.
[499] *See* CSA – Compliance, Dkt. # 1924; Rafalski Rep., Dkt. # 2000-22 at 40-44; and Whitelaw Rep., Dkt. # 2000-26 at 44-48.
[500] *See* CSA – Compliance, Dkt. # 1924; Rafalski Rep., Dkt. # 2000-22 at 46-142.

(N.D. Ohio 2011) (citing *Williams*) ("Civil conspiracy does not require the existence of a duty on the part of the alleged co-conspirator. Rather, there must simply be evidence of a common understanding or design to commit an unlawful act.).

The Pharmacy Defendants rely on *Parker v. Eli Lilly*, No. CV-274501, 1996 WL 1586780, at *3 (Ohio C.P. Jun. 21, 1996), but that case is factually inapposite. (Dkt. # 1716 at 14-15). In *Parker,* there was no evidence that the conspirators had a way to know that a specific application of a drug was wrongful at the time they were meeting, and no evidence of any later agreement or coordination concerning defendants' individual actions. 1996 WL 1586780 at *3. Here, it is undisputed that all Defendants knew the CSA requirements and the harms they were intended to prevent, both before and throughout the course of their communications and actions.[501]

Similarly misplaced is the Distributor Defendants' reliance on *FV 1 Inc. v. Goodspeed*, 974 N.E.2d 664, 678 (Ohio Ct. App. 2012). (Dkt. # 1692 at 13-14). In *FV1*, while the court found a mortgage broker may have breached its duty to a home purchaser by improperly delegating certain duties to an unqualified person who violated the law, the court rejected conspiracy claims where there was no evidence that the broker had knowledge of the fraudulent acts and the plaintiff admitted there was no evidence to support malice or concerted action and plaintiff testified he did not believe the defendants knowingly engaged in wrongful acts. *Id.* Here, the record is replete with evidence of Defendants' knowledge of the wrongful actions and of their deliberate cooperation to accomplish them.

Further, Plaintiffs' burden in opposing summary judgment is not to "exclude the possibility" that the Defendants' conduct could be independent action.[502] (Dkt. # 1692 at 6; Dkt. # 1716 at 5). It is well-established that in opposing summary judgment plaintiffs are required only to adduce evidence

[501] *See* CSA – Compliance, Dkt. # 1924.
[502] Defendants cite a number of antitrust cases, which are inapplicable as to the burden of proof here.

from which a tacit agreement may reasonably be inferred, and as the record shows, Plaintiffs have met that burden.

The record shows that, despite instituting nominal controls, Defendants sold and shipped extraordinary volumes of opioids over an extended period of time.[503] To that end, when Defendants instituted SOM programs, the programs were deliberately ineffective and permissive, with constantly shifting boundaries to accommodate the ever-growing orders being placed by their customer stores.[504] The fact that Defendants employed nominally different SOM systems does not unseat the conspiracy. The systems all shared one key characteristic: each system was largely "window dressing" and failed to timely report or halt shipment of suspicious orders.[505]

Even after regulatory actions made it clear that the systems Defendants were using were not compliant, the Defendants still failed to implement effective programs. For example, after the 2008 regulatory action against its secondary supplier, Cardinal Health, Walgreens claimed it was instituting an updated SOM program in response to that action, but instead, wrote a sieve-like plan and took four years to implement it.[506] Similarly, though Cardinal Health and McKesson claimed they were complying with the CSA as dictated by their 2008 agreements with the DEA, the 2016 and 2017 DEA actions against them and the testimony of the DEA confirm that, not only were they not complying with the CSA, but they were "blatantly" violating their 2008 agreements. *See supra,* pp. 42.[507]

Defendants further argue that the fact that *some* Defendants began to report *some* suspicious orders in 2013 disproves the conspiracy (Dkt. # 1692 at 15-16), but that minimal reporting occurred only after the DEA initiated additional regulatory actions and investigations into many of the

[503] *See* Rafalski Rep., Dkt. # 2000-22 at 40-45, 47; and McCann Rep., Dkt. # 2000-14 at 82-88.
[504] *See* CSA – Compliance, Dkt. # 1924; Rafalski Rep., Dkt. # 2000-22 at 46-186.
[505] See CSA – Compliance, Dkt. # 1924; Rafalski Rep., Dkt. # 2000-22 at 46-186; Whitelaw Rep., Dkt. # 2000-26 at 44-48.
[506] *See* CSA – Compliance, Dkt. # 1924.
[507] *See* Thomas Prevosnik Dep. (04/18/19), Dkt. # 1969-13 at 621:5 - 621:20, 621:5 - 621:16.

Defendants around 2012.[508] Even then, Defendants only reported a tiny fraction of suspicious orders and continued to ship.[509]

The record thus contains sufficient evidence to conclude Defendants' failures to comply with the CSA were not independent parallel conduct, but actions in furtherance of their conspiratorial objective.

3. Defendants' Actions are Not Legitimate Business Activities

Defendants argue that their distribution activities comprise legitimate business activity. *See* Dkt. # 1716 at 8, 16 ("Pharmacy Defendants …[were] engag[ed] in legitimate business activities involving the distribution… [and a] "rational and competitive business strategy."). But Defendants were not entitled to distribute opioids without complying with their legal duties to maintain effective controls against diversion and report and halt suspicious orders.

Defendants knew the fulfillment of their legal duties was necessary to "protect the American people from [the] extraordinary threat to public health and safety" posed by prescription narcotics, *Southwood Pharmaceuticals, Inc.; Revocation of Registration,* 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007), and knew their practices were not within the bounds of legal commercial activities or relationships. Many of the Defendants have admitted to violating those duties during the DEA's repeated regulatory actions against them, and yet Defendants continued to violate the rules and even their agreements with the DEA. *See supra,* pp. 42.[510] As McKesson stated about its new SOM program immediately after being sanctioned by the DEA in 2008, "[t]his program … ensures you as a McKesson customer can continue with business as usual." The fact that noncompliance was Defendants' normal course of practice does not make it legitimate. The DEA testified, through Thomas Prevosnik, that that it was "frustrated that registrants were blatantly violating the

[508] Rafalski Rep., Dkt. # 2000-22 at 21-31; Rafalski Rep., Dkt. # 2000-22 at 50-51, 72-73, 89.
[509] Rafalski Rep., Dkt. # 2000-22 at 40-46.
[510] Rafalski Rep., Dkt. # 2000-22 at 21-31.

MOUs[/MOAs] from prior administrative actions" including both Cardinal and McKesson, who the DEA said "blatantly" violated the memoranda of agreement from their 2008 regulatory actions, resulting in additional actions and fines against each company in 2016 and 2017. *See supra,* pp. 42.[511]

Defendants cannot shield their wrongful actions from liability merely because they were conducted through legitimate business relationships. Even in an antitrust case, which carries a higher standard of proof, "business behavior is admissible circumstantial evidence from which the fact-finder may infer [a conspiratorial] agreement," *Nurse Midwifery Associates v. Hibbett*, 918 F.2d 605, 616 (6th Cir. 1990) (quoting *Theatre Enters., Inc. v. Paramount Film Distrib. Corp.*, 346 U.S. 537, 540 (1954)). "A conspiracy can be established by showing that business behavior evidenced 'a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement.'" *Id.* (citing *American Tobacco Co. v. United States*, 328 U.S. 781, 810 (1946)).[512]

Like the RICO Manufacturers, the Pharmacy Defendants rely heavily on *Woodward*, 30 N.E.3d 237, for the proposition that participation in a business transaction is insufficient to establish a conspiracy. *Woodward* is inapposite, however, because there was "*no evidence"* the alleged conspirator "directed, solicited, or knew of" the wrongful actions. *Id.* at 244 (emphasis added). Here, there is ample evidence Defendants knew of each other's wrongful actions, and directed and solicited agreement with the conspiratorial objective, and worked with each other to achieve it.

Similarly inapplicable is the decision in *United Food & Commercial Workers Unions & Emp'rs Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 855 (7th Cir. 2013) where the only evidence of cooperation was merely that "inherent in every commercial transaction" and fell within "the bounds of the parties' normal commercial relationships," without any evidence of cooperation to accomplish the illegal activity. Here, the evidence shows cooperation between the Defendants expressly designed

[511] *See* Thomas Prevosnik Dep. (04/18/19), Dkt. # 1969-13 at 621:5 to 621:20.

[512] The *Nurse Midwifery* court ultimately found no conspiracy under the Sherman Act due to the special requirement in antitrust cases to "present evidence 'that tends to exclude the possibility' that the alleged conspirators acted independently." *Id.* That additional affirmative requirement is not present here.

to circumvent the CSA duties and controls meant to protect the public from these highly dangerous and controlled drugs.

Like the RICO Defendants, Defendants argue (Dkt. # 1716 at. 12-14; Dkt. # 1692 at 18) that legitimate trade association activity cannot be the basis of liability. That argument should be rejected for the reasons explained above. *See supra*, 80; *see also City of Milwaukee v. NL Industries, Inc.*, 691 N.W.2d 888, 896 (Wis. Ct. App. 2004) (denying summary judgment on conspiracy claim in part based on trade group's "involvement in lead paint promotion and opposition to regulatory legislation"); *In re North Dakota Personal Injury Asbestos Litigation No. 1*, 737 F. Supp. 1087, 1096-1098 (D.N.D. 1990) (finding that "group decisions" carried out through a trade organization "tend[ed] to show a meeting of the minds and an agreement to accomplish" the goals of the conspiracy). Defendants' cited cases are entirely inapposite and add nothing new.

4. Plaintiffs' Conspiracy Claims Against the Pharmacy and Distributor Defendants are Not Based on Opioid Marketing

The Distributor and Pharmacy Defendants argue there is no evidence that Distributors and Pharmacies fraudulently marketed opioids. *See* Dkt. # 1692 at 10-14; Dkt. # 1716 at 2-4. It is not from that activity which Plaintiffs ask the Court to find distributors and pharmacies entered into or carried out the conspiracy.

As shown above, the conspiracy began with the Manufacturer Defendants' false marketing efforts and then extended to the distributors and pharmacies, who later joined the conspiracy when manufacturers determined they needed distributors and pharmacies to participate in order to protect the supply chain and expand the market. *See supra,* pp. 7-26, 27-73.[513] It is not necessary for the Distributor and Pharmacy Defendants to have joined in the Manufacturers false marketing to be part of the conspiracy. *Weberg v. Franks*, 229 F.3d 514, 526 (6th Cir. 2000) (citing *Hooks v. Hooks*, 771 F.2d

[513] *See, e.g.*, Exh. 670, PDD1701421278; Exh. 202, PKY181715440; Exh. 237, PPLPC053000021255; Exh. 243, PPLPC018000200323; Exh. 244, PPLPC004000146532; Exh. 248, CAH_MDL2804_00879572; Exh. 280, PPLP004473400; Exh. 232, CAH_MDL_PRIORPROD_DEA07_00842131; Exh. 241, MNK-T1_0000559532; Exh. 242, MNK-T1_0000506535.

935, 943–44 (6th Cir. 1985)) ("Each conspirator need not have known all of the details of the illegal plan or all of the participants involved"); *United States v. Mayes*, 512 F.2d 637, 642 (6th Cir. 1975) (proof that "each defendant knew or was involved with all of the activities of all other defendants" is "not an essential element of proving a single conspiracy."). Rather, it is sufficient that the Distributor and Pharmacy Defendants "shared [the] general conspiratorial objective" and had "a common understanding" to "disregard drug reporting obligations [and other anti-diversion duties] to effectuate that goal."[514]

A single conspiracy may be broad ranging, "continu[ing] over a long period of time" and may "contemplate[] the commission of many illegal acts," and may "involve[] many people" and a "large geographic area." *Mayes*, 512 F.2d at 642-43. The members of a conspiracy thus need not be static, nor are members solely liable for actions that occur while they are active members. Conspirators may be held liable for actions in furtherance of the conspiracy, even when those actions occurred prior to that member joining. *See In re Welding Fume Products Liab. Litig.*, 526 F. Supp. 2d 775, 802 (N.D. Ohio 2007) (noting that "'person who joins an existing conspiracy will be held liable for what was previously done pursuant to the conspiracy. . . [if it is] shown that he or she joined the conspiracy with knowledge of the unlawfulness of its object or of the means contemplated'") (quoting 16 AM. JUR.2d *Conspiracy* § 57 (2007)).[515] And even if the Court were to determine that the summary judgment record is deficient as a matter of law to create a genuine issue of material fact as to any particular individual defendant's participation in the conspiracy, the Court should nevertheless deny summary judgment as to the other members of the conspiracy.

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[514] *In re: Nat'l Prescription Opiate Litig.,* 2018 WL 6628898, at *11.

[515] *See also* 16 AM. JUR.2d *Conspiracy* § 57 ("The joint and several liability of a conspirator applies to damages accruing prior to his or her joining the conspiracy as well as damages thereafter resulting-regardless of whether he or she took a prominent or an inconspicuous part in the execution of the conspiracy. This liability of each member of a conspiracy for the damage resulting therefrom exists whether or not the conspirator profited from the result of the conspiracy. Before a person who joins an existing conspiracy will be held liable for what was previously done pursuant to the conspiracy, however, it may be shown that he or she joined the conspiracy with knowledge of the unlawfulness of its object or of the means contemplated.").

5. The Pharmacy and Distributor Defendants' Conduct is Not Protected by the First Amendment

Like the RICO Supply Chain Defendants, the Pharmacy and Distributor Defendants argue that the *Noerr-Pennington* doctrine immunizes them from liability for their lobbying efforts. However, as explained above, the *Noerr-Pennington* doctrine is inapplicable here where Plaintiffs do not attempt to impose liability upon the Pharmacy or Distributor Defendants for their lobbying activities, or argue that the lobbying was unlawful conduct. *See supra*, pp. 87-88.

6. Defendants Have Not Withdrawn from the Conspiracy

There is no evidence that any of the Defendants have withdrawn from the conspiracy. Conspirators remain in the conspiracy – and remain liable for the actions of the conspiracy – until they affirmatively withdraw. *Mayes*, 512 F.2d at 642-43 ("[W]here a conspiracy contemplates a continuity of purpose and continued performance of acts, it is presumed to exist until there has been an affirmative showing that it has terminated; and its members continue to be conspirators until there has been an affirmative showing that they have withdrawn."). A coconspirator does not withdraw from a conspiracy simply when he suspends certain of his overt actions, but rather must affirmatively withdraw. *See United States v. Brown*, 332 F.3d 363, 374 (6th Cir. 2003) (Withdrawal is an "affirmative defense," and "[t]he defendant carries the burden of proving withdrawal and must show that he took affirmative action to defeat or disavow the purpose of the conspiracy. Without such action, liability continues for all actions in furtherance of the conspiracy by other conspirators.").

Even reaching a DEA settlement regarding some of the coconspirator's own overt actions may be insufficient to effectuate withdrawal, particularly where the conspirator otherwise continued to support the conspiracy's objectives. *Watson Carpet & Floor Covering, Inc. v. Mohawk Indus., Inc.*, 648 F.3d 452, 460 (6th Cir. 2011) ("Shrewd conspirators may not pursue conspiratorial objectives with impunity simply by settling early in the conspiracy."); *see also Williams* 700 N.E.2d at 868 (quoting Prosser & Keeton on Torts (5 Ed.1984) 323, Section 46) ("All those who, in pursuance of a common plan or design to commit a tortious act, actively take part in it, or further it by cooperation or request,

or who lend aid or encouragement to the wrongdoer, or ratify and adopt the wrongdoer's act done for their benefit, are equally liable.").

Of particular note, many of the Pharmacy Defendants that ceased self-distributing opioids to their chain pharmacies in or around 2014 have continued to work with the outside Distributors that took over distribution to make sure that the nominal SOM systems now being employed do not impede the flow of opioids through the chain pharmacies. *See supra,* pp. 59-73. Neither ceasing self-distribution, nor entering into a settlement agreement with the DEA, has ended Defendants' membership in the Conspiracy.

II. DEFENDANTS' ACTIONS SUPPORT CLAIMS FOR PUBLIC NUISANCE, OHIO RICO, AND INJURY THROUGH CRIMINAL ACTS, EACH OF WHICH CAUSED PLAINTIFFS' DAMAGES

Defendants' wrongful actions in furtherance of the conspiracy also constitute underlying torts, including Public Nuisance, Ohio RICO, and Injury Through Criminal Acts. *See, supra*, at pp. 74-101. As this Court has already held, "any of these claims is sufficient to satisfy the underlying wrongful act element" for civil conspiracy under Ohio law. *In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at *11. *See Gosden*, 687 N.E.2d at 496-497 (The "unlawful act" is satisfied by the commission of an underlying tort in furtherance of the conspiracy). Other than RICO and OCPA, Defendants do not address any of these claims in their RICO and Conspiracy motions, but rather the Pharmacies claimed those arguments would be made in other "forthcoming motions." Dkt. # 1716 at 18. While Pharmacies failed to file separate motions regarding Nuisance or Injury Through Criminal Acts claims, and thus have not met their burden of establishing those claims should be dismissed, Plaintiffs generally incorporate by reference Plaintiffs' Memorandum in Opposition to Manufacturer Defendants' Motion for Summary Judgment on Plaintiffs' Public Nuisance Claims (PSJ7) and also this Court's prior ruling upholding Plaintiffs' Nuisance and Injury through Criminal Act claims. *See In re National Prescription Opiate Litigation*, 2018 WL 6628898, at ** 12-15, 20.

Additionally, contrary to the Pharmacy Defendants' argument, Plaintiffs are *not* required to show damages separately arising from the conspiracy. *Gosden*, 687 N.E.2d at 498 (finding that the *Crosby* decision cited by the Pharmacies is "based on a misreading" of Ohio caselaw and holding "[a] civil conspiracy claim … serves only to enlarge the pool of potential defendants from whom a plaintiff may recover damages and, possibly, an increase in the amount of those damages; it does not increase the plaintiff's burden by requiring proof of additional damages."); *accord, Javitch*, 2011 WL 1002744. Plaintiffs' damages arise from the "tort committed in furtherance of the conspiracy," such that "the measure of recovery for a conspiracy claim" is the "damages caused by the underlying tort (or torts)." *Id.*

The opioid market cannot be legitimately grown by excessive sales in violation of legal duties. In *Direct Sales*, the Court noted opioids' "inherent[] … susceptibility to harmful and illegal use" such that "drug addicts furnish the normal outlet for morphine which gets outside the restricted channels of legitimate trade." 319 U.S. at 710. The Court found that "the market for opiates may [not] be developed as any other market" and that efforts to increase the market that might be appropriate with other commodities are not for opioids because, with respect to opioids, "[t]hey do not create new legal demand and new classes of legitima[t]e patrons" because "the normal legal market for opiates is not capable of being extended by such methods." *Id.* Rather, "[t]he primary effect is … to create black markets for dope and to increase illegal demand and consumption." *Id.* Indeed, these were the very concerns which spawned the Controlled Substance Act in 1970 [516] and the effective controls against diversion which registrants are required to maintain in order to sell these dangerous drugs, but which these Defendants deliberately disregarded in pursuit of their common objective to protect and grow their opioid sales.

[516] *See* Memorandum in Support of Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act ("CSA Duties"), Dkt. # 1887.

CONCLUSION

For the foregoing reasons, this Court should deny the motions for summary judgment.

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Respectfully submitted,

/s/Paul J. Hanly, Jr.
Paul J. Hanly, Jr.
SIMMONS HANLY CONROY
112 Madison Avenue, 7th Floor
New York, NY 10016
(212) 784-6400
(212) 213-5949 (fax)
phanly@simmonsfirm.com

/s/ Joseph F. Rice
Joseph F. Rice
MOTLEY RICE
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
(843) 216-9000
(843) 216-9290 (Fax)
jrice@motleyrice.com

Paul T. Farrell, Jr., Esq.
GREENE KETCHUM, LLP
419 Eleventh Street
Huntington, WV 25701
(304) 525-9115
(800) 479-0053
(304) 529-3284 (Fax)
paul@greeneketchum.com

Plaintiffs' Co-Lead Counsel

/s/ Peter H. Weinberger
Peter H. Weinberger (0022076)
SPANGENBERG SHIBLEY & LIBER
1001 Lakeside Avenue East, Suite 1700
Cleveland, OH 44114
(216) 696-3232
(216) 696-3924 (Fax)
pweinberger@spanglaw.com

Plaintiffs' Liaison Counsel

Hunter J. Shkolnik
NAPOLI SHKOLNIK
360 Lexington Ave., 11th Floor
New York, NY 10017
(212) 397-1000
(646) 843-7603 (Fax)
hunter@napolilaw.com

Counsel for Plaintiff Cuyahoga County, Ohio

Linda Singer
MOTLEY RICE LLC
401 9th St. NW, Suite 1001
Washington, DC 20004
(202) 386-9626 x5626
(202) 386-9622 (Fax)
lsinger@motleyrice.com

Counsel for Plaintiff Summit County, Ohio

On the Brief:

BARON & BUDD, P.C.

Mark Pifko
Sterling L. Cluff
Baron & Budd, P.C.
15910 Ventura Boulevard, Suite 1600
Los Angeles, CA 91436

Catherine Hancock Dorsey
600 New Hampshire Avenue NW
10th Floor
Washington, DC 20037

Christine C. Mansour
3102 Oak Lawn Avenue, Suite 1100
Dallas, TX 75219

CRUEGER DICKINSON

Charles Crueger
Erin Dickinson
4532 N Oakland
Whitefish Bay, WI 53211

LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.

Page A. Poerschke
Laura S. Dunning
316 S. Baylen Street, Suite 600
Pensacola, FL 32502-5996

THE LANIER LAW FIRM

Rebecca L. Phillips
6810 Cypress Creek Parkway
Houston, TX 77069